Densitometry RX

EXA-3000

Health Fit & Sport Group

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Thank you for purchasing **EXA-3000** X-ray Bone Densitometer. To ensure safe operation and long-term performance stability, it is essential that you fully understand the functions and operating, maintenance instructions by reading this manual before operating the equipment.

Particular attention must be paid to all warnings, cautions and notes incorporated herein.

Incorrect operation, or failure of the user to maintain the equipment relieves the manufacturer or his agent of the system's noncompliance with specifications or of responsibility for any damage or injury.

The following conventions are used throughout the manual to denote information of special emphasis.

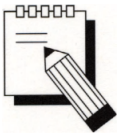
WARNING !
"Warning" is used to indicate the presence of hazard that can cause severe personal injury, death or substantial property damage if the warning is ignored.

CAUTION !
"Caution" is used to indicate the presence of hazard that will or can minor personal injury and property damage if the caution is ignored.

NOTE !
"Note" is used to notify the user of installation, operation or maintenance information that is important but not hazard related.

The symbols which are shown in this manual

The noticed information which should be concerned with explanation in this manual



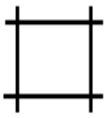
The noticed information when the device is operated.

The reference page or section.

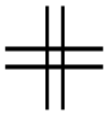
The symbols which are shown on EXA-3000.

X-ray On
- A Symbol that shows the location of the X-ray On light. It is also shown on the screen during quality control and patient measurements when EXA-3000 is making X-rays.

X-ray Source
- A symbol shown on the screen during quality control and patient measurements when EXA-3000 is not making X-rays.



Shutter Open
- A symbol that shows the location of the Shutter Open light. It is also shown on the screen during quality control and patient measurements when the shutter is not fully closed.



Shutter Closed
- A symbol shown on the screen during quality control and patient measurements when the shutter is closed.

Power On
- A symbol that shows the location of the Power On light.

Start
- Appears on a button if EXA-3000 will make X-ray when you select the button.

Communication Failure
- A symbol that appears on screen in place of the X-ray On symbol during a measurement if the computer loses contact with EXA-3000.
- Make sure the X-ray On light on EXA-3000 is off if this symbol appears. If the light is not off, turn off EXA-3000

I and O on power switch represent ON and OFF, respectively.

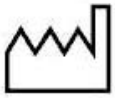
The Attention symbol that marks warning and important information in the user's manual.

The conductor provides a connection between equipment and the potential equalization bus-bar of the electrical installation.

Indicates dangerous voltage over 1000VAC or over 1500 VDC.

Identifies the point where the system safety ground is fastened to the chassis. Protective earth connected to conductive parts of Class II equipment for safety purpose.

Applied Part Type B



The date of manufacture

Radiation
- A symbol that shows this equipment makes radial rays.

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Chapter 1. Introduction

1.1 General Product Information

Osteoporosis is one of the serious diseases. This device is a bone densitometer which estimates a bone mineral density of the forearm and calcaneus by X-ray.

It takes about 10 seconds to measure the density and to display that image on the monitor.

To ensure safe operation and long-term performance stability, it is essential that you fully understand the functions, operating and maintenance instructions reading this manual before operating the equipment.

※ Features and Cautions !

- This device is an X-ray bone densitometer which has 1.5% precision error.
- The equipment must be operated only by, or under supervision of a qualified person.
- When you give the appropriate commands in EXA3000 software, X-rays are generated. A collimator directs the X-ray through the Patient's forearm or calcaneus to the detector, where the X-ray screen and CCD(charge coupled device) camera detect the radiation.
- The detected radiation image is treated by EXA algorithm.
- EXA-3000 software calculates the ROI(Region of Interest) and displays the patient's bone density.
- All operators must understand the potential hazards in the use of medical electronic devices and X-ray devices. They must be able to recognize hazards and protect themselves and others from injury.
- The computer and the operator should be placed at least 2.0m from EXA-3000 being operated. However the USB cable length should not be longer than 3.0m.
- Never remove any system covers. Especially, the X-ray generator which contains up to 80 Kvolts. That can injure you.
- If the fuses are gone, exchange the same type (250V T315AL). Otherwise a fire may occur or you may receive electric shock.
- In case of changing the PC or the printer for other products, check them according to IEC/EN60601-1-1.
- Unplug the power cord before you move or clean the device and after using EXA-3000
- For installation and operation of this equipment national regulation shall be considered.

Chapter 2. Configuration of EXA-3000

2.1 Composition of EXA-3000

2.1.1 Shape and Components of EXA-3000

2.1.2 Shape and Components of Measurement Equipment

2.1.3 Keyboard

2.1.4 Accessories List

2.1.5 Articles List

2.2 Installation of EXA-3000

2.3 Installation of Lifter

2.4 Before Turning on Power

2.1 Composition of EXA-3000

2.1.1 Shape and Components of EXA-3000

<Front View>

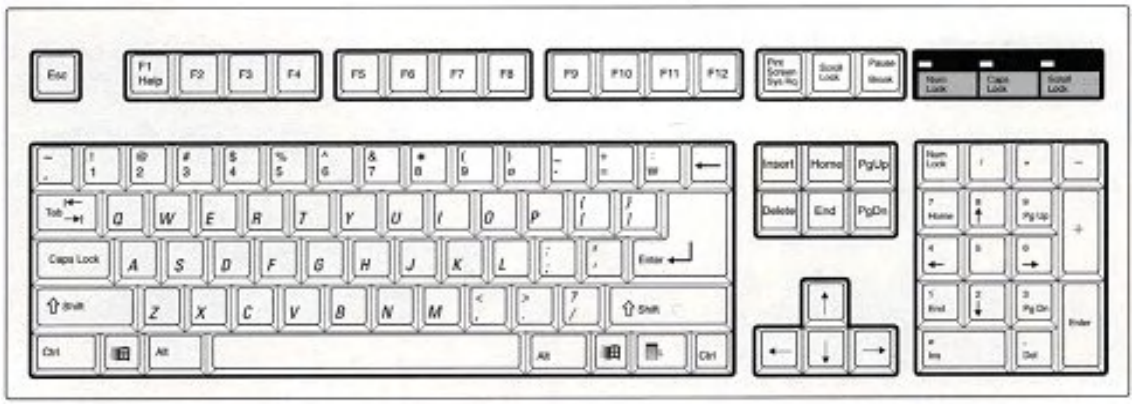
2.1.2 Shape and Components of Measurement Equipment

EXA-3000

(1) Heel Positioner

: When measuring calcaneus, the heel positioner holds the foot.

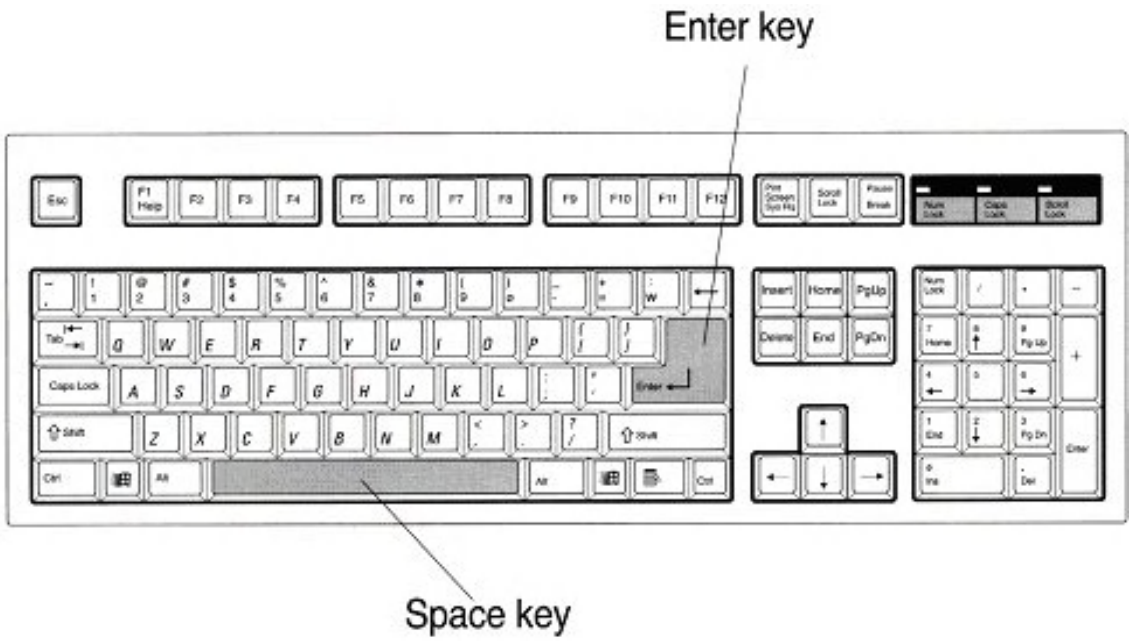
2.1.3 Keyboard



Keyboard

Activate EXA-3000 by pressing a key on the keyboard according to the instructions shown on the monitor.

The manual shows keys required to activate EXA-3000 as shown below.



2.1.4 Accessories List

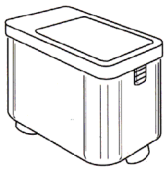
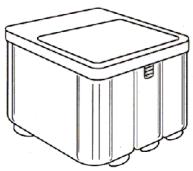
Accessories marked "*" is articles of consumption

4.2.2 Stockpiles and Replacement of Articles

Names of Products	Number	Uses
User's manual	1	Make sure to keep it at a designated place so that users can read it anytime they need to.
QC Phantom (Daily Phantom)	1	It is used to calibrate the system.
Power Cable	1	It is used to connect to the source of electric power with the main body of EXA-3000.
USB Cable	1	It is used to connect to the computer with the main body of EXA-3000.
Program CD	1	It is used to install the program on the computer.(The program is installed on the computer before being delivered)

2.1.4 Articles List

4.2.2 Stockpiles and Replacement of Articles

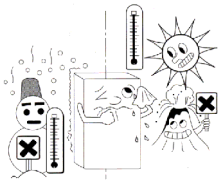
Names of product	Shape	Number	Specifications
Ink Cartridge	Black 	1	Manufacturer: HP 3820
	Color (3 colors) 	1	Manufacturer: HP 3820

2.2 Installation of EXA-3000

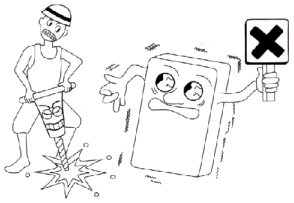
NOTE !
Since EXA-3000 is made up of precise components, you should install the product according to instructions below.

Do not install and keep EXA-3000 at excessively high or low temperatures.

Proper temperature: 18~27 ℃

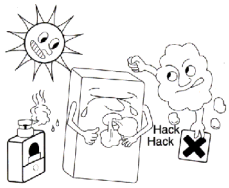


Do not install or keep EXA-3000 in a place where the machine can be rocked or shaken.
Make sure to place the system parallel to the floor.

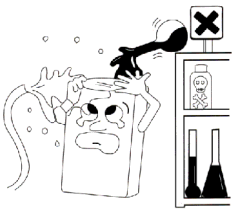


Do not install the system in a place with polluted air and high humidity and do not expose the machine to direct ray sunlight. It is advisable to use EXA-3000 in a place equipped with air conditioning or heating.

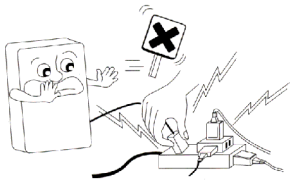
Proper humidity: 20~80%



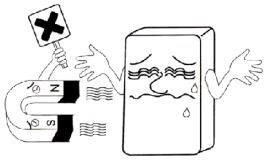
Install EXA-3000 in the place where it is free from water or chemicals.



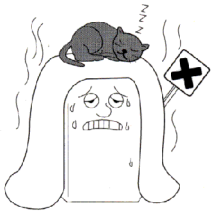
Do not share the power outlet with other products through an extension cord.



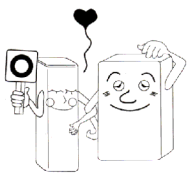
Do not use the system near equipment that generates strong magnetic fields.



Do not cover ventilation of the system or place it near the wall. High inside temperature of the machine might cause a fire.

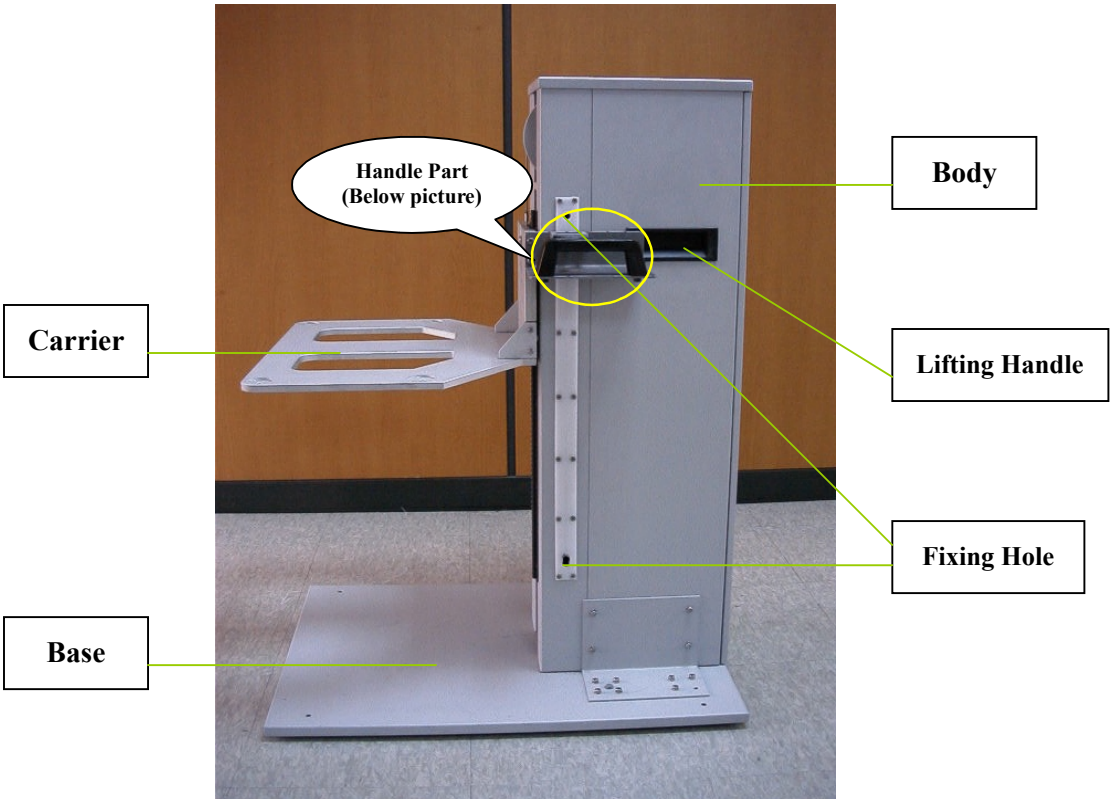


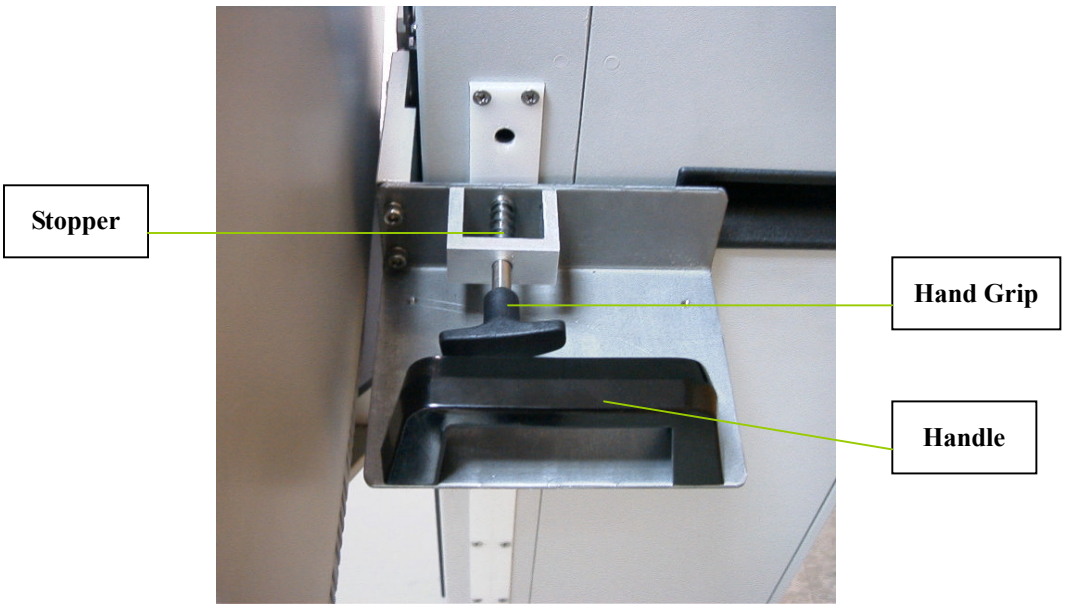
100-240V is usable.
When EXA-3000 is taken out of a warehouse, insulating transformers should be set to 100-240V. Since sudden power outage can remove all data saved in the product, you should install EXA-3000 in the place where a power supply is stabilized.



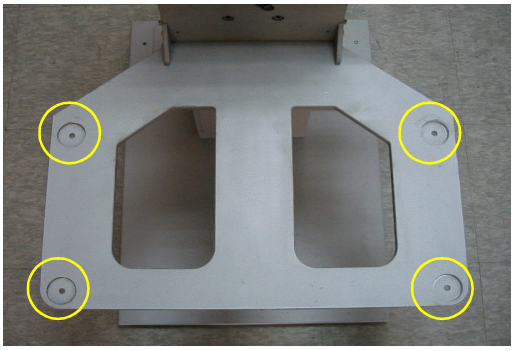
2.3 Installation of Lifter

(1) Shape and Components of Lifter





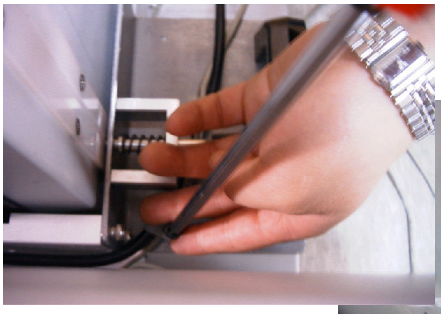
(2) Fixing the device



- There are four fixing holes in the carrier for fixing the device. On the other hand, there are four holes in the base of the device and they are fastened with each bolt.
- To fix the device in the lifter, remove the blots from the base of the device using a tool and match each hole after placing the device on the carrier.
- Then fasten with the bolts(removed from the base of the device) as shown above.

NOTE !
For the safety, you should fix the device in the lifter. Otherwise the device can be dropped from the lifter when you adjust the height of the lifter or be inattentive.

(3) Fixing the USB Cable & Power Cable



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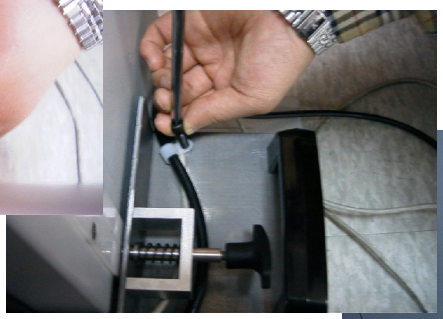


ⓑ

ⓒ

- There are three fixing holes in the body and the handle part for fixing the USB cable & power cable.
- After plugging each cable into the connector of the device, arrange the cables and fix the cables using clamps and blots. We recommend you to work according to the order(ⓐ→ⓑ→ⓒ) as shown above.

NOTE !
For the safety, you should fix the USB cable & power cable in the lift. Otherwise the cables can be jammed in the lifter and they can cause some trouble when you adjust the height of the lifter or be inattentive.

(4) Adjusting the height of the Lifter

- If you want to adjust the height of the lifter, pull the hand grip after holding the handle as shown above. (The stopper will be separated from the fixing hole.)
- Then adjust the height of the lifter with care and insert the stopper in the fixing hole.

CAUTION !
Be sure to fix the device in the lifter before adjusting the height of the lifter. Otherwise the carrier can be bounced suddenly by the pressure of the gas spring in the lifter, and you can be injured.

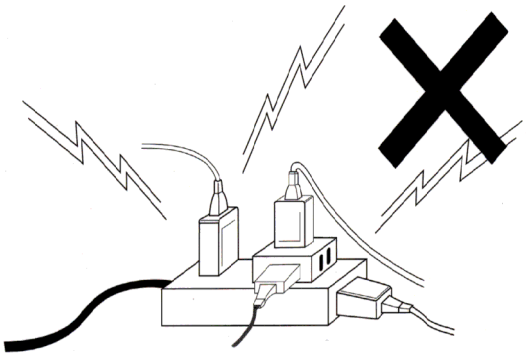
2.4 Before Turning on Power

(1) Connection of USB Cable

Plug in the USB cable.

Plug into the connector.
When you detach the USB cable from the main body of EXA-3000, do not hold the cable and instead hold the connector. Otherwise wire could be down.

(2) Connection of Power Cable



Avoid sharing the outlet.

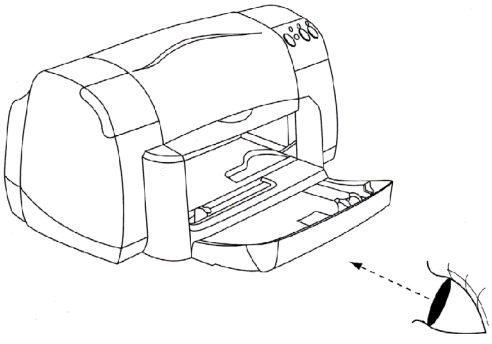
CAUTION !

- Make sure that the covering of cable is not damaged to prevent electric shock or short circuit.
- If you find any damage or any sign of it, immediately contact an agency.
- Put the Power cord into only one plug
- Make sure not to share the power outlet to prevent EXA-3000 from being affected.

(3) Make sure that paper is properly provided to the printer.

Supply of paper

4.2.2 Stockpile and Replacement of Articles



Chapter 3. Using EXA-3000

3.1 Using H/W

3.1.1 Forearm Acquisition

3.1.2 Os Calcis Acquisition

3.2 Using S/W

3.2.1 Progress Table of Program

3.2.2 How to install the program

3.2.3 Using Program

3.2.3.0 Installation of USB Driver

3.2.3.1 Execution of Program and Configuration of the Incipient Environment

3.2.3.2 Registration & Deletion of Users

3.2.3.3 BMD Measurement

3.2.3.4 Revision & Deletion of Patient's Information

3.2.3.5 Inquiry & Deletion Clinical History of Existing Patients

3.2.3.6 Calibration of EXA-3000

3.2.3.7 Data Backup

3.2.3.8 Configuration of Environment

3.2.3.9 Inactivation of EXA-3000

3.1 Using H/W

3.1.1 Forearm Acquisition

1) Adjust the height of the lifter for measuring a patient's forearm.(The device should be placed 50cm or more away from a table or floor.)
2) Set EXA-3000 for the forearm acquisition mode.
3) There is the base line on the heel positioner as shown below. Put a wrist part on the base line and place it as close to the right side(detector) as possible in order to keep the absorbed dose to patients low as shown below.

< Forearm default positon >

4) In times of making X-rays, pull up sleeves and take off accessories such as wrist watches or bracelets.(Make sure not to place any things besides the forearm in the slot, it may arise some adverse effect during the measurement.)
5) Make sure patients do not move their wrist while you make X-rays.

< Left Forearm>

< Right Forearm >

3.1.2 Os Calcis Acquisition

1) Adjust the height of the lifter for measuring patients' Os Calcis.
2) Set EXA-3000 for the Os calcis acquisition mode as shown below.

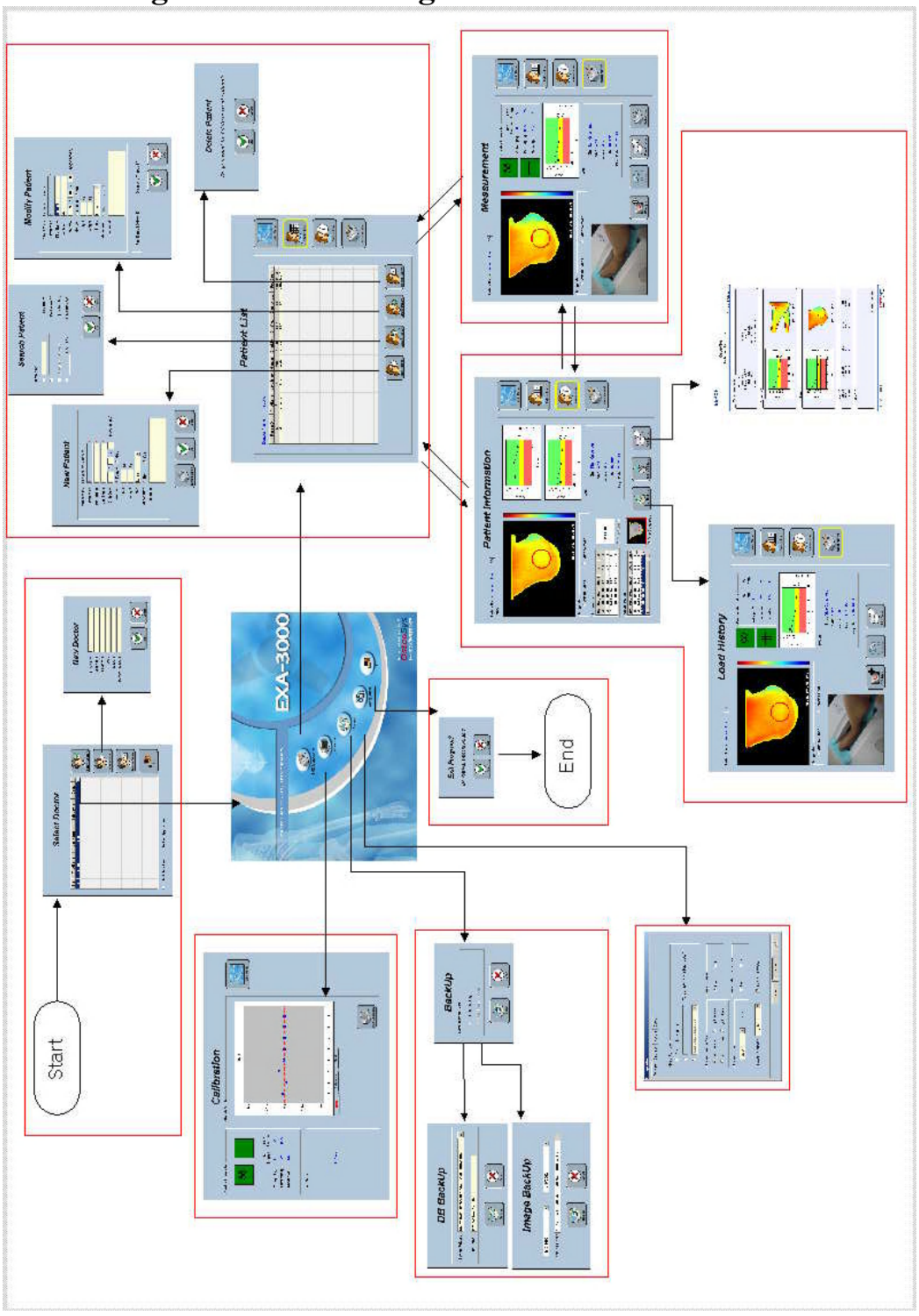
< Moving the heel positioned for heel measurement >

3) Place a foot as close to the right side(detector) as possible in order to keep the absorbed dose to the patient low as shown below.
4) Let patients take off their shoes before making X-rays. Patients do not have to take off their socks or stockings, but if they are wearing thick socks or something that includes metal, make sure they take them off.(Make sure not to place any things besides the foot in the slot, it may arise some adverse effect during the measurement.)
5) Make sure patients do not move their foot while you make X-rays.

< Left Os Calcis> **< Right Os Calcis >**

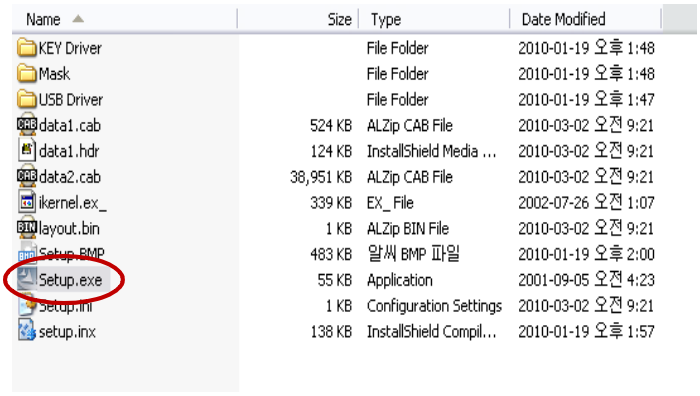
3.2 Using S/W

3.2.1 Progress Table of Program



3.2.2 How to install the program

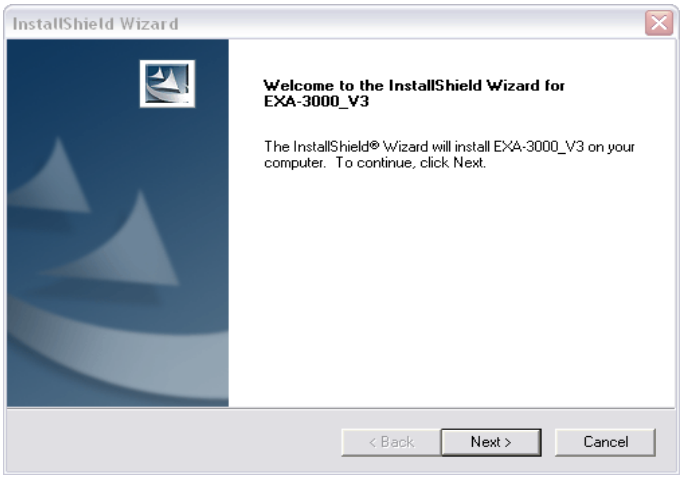
1) Enter the folder in ‘ Setup.exe’ file



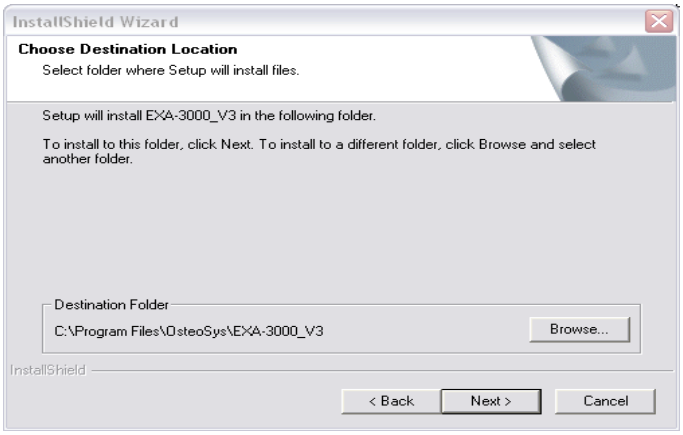
2) Click the Setup.exe.

3) The installation starts when the following image is shown .

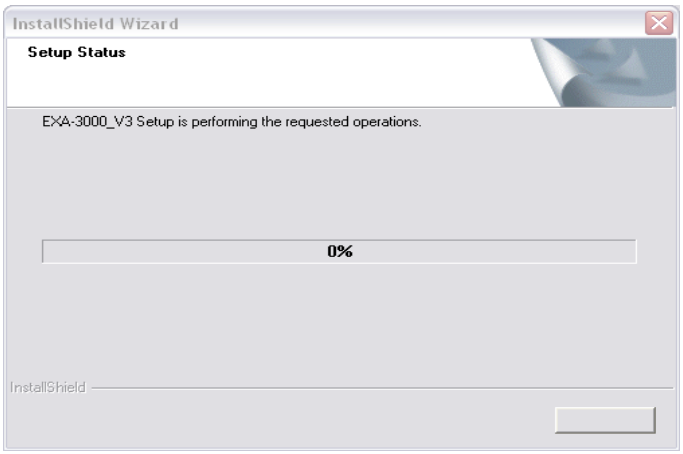
4) Click ‘Next’ Button.


InstallShield Wizard
Welcome to the InstallShield Wizard for EXA-3000_V3
The InstallShield® Wizard will install EXA-3000_V3 on your computer. To continue, click Next.
< Back
Next >
Cancel

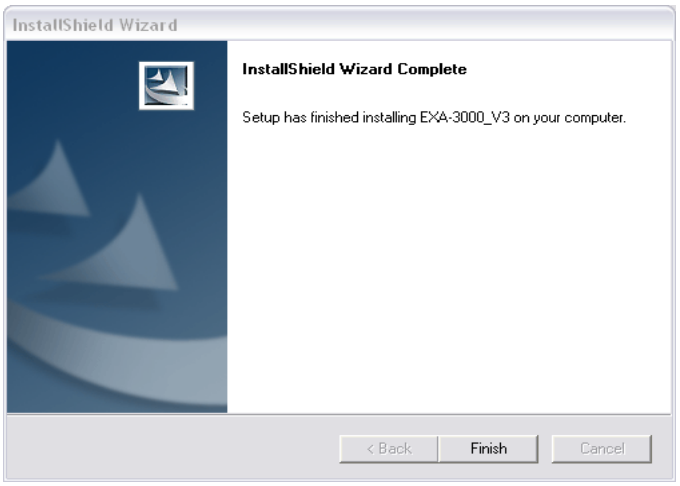
5) Click ‘Next’ Button.


InstallShield Wizard
Choose Destination Location
Select folder where Setup will install files.
Setup will install EXA-3000_V3 in the following folder.
To install to this folder, click Next. To install to a different folder, click Browse and select another folder.
Destination Folder
C:\Program Files\OsteoSys\EXA-3000_V3
Browse...
InstallShield
< Back
Next >
Cancel

6) The installation starts



7) The installation is done.



3.2.3 Using Program

3.2.3.0 USB Driver installation

3. CAUTION !
If OS is Window Vista or Window7, USB Driver is not installed automatically. Install USB Driver as following procedure.

(1) Execute EXA 3000's install CD.

(2) USB Driver folder in CD -> New Device

Ex) If CD path is E:\;

E:\ USB Driver\New Device

(3) If Vista,

A. Move to "New Device\Vista" folder,

double click [Osteosys_Exa3k_1.0.810.23316_release .exe] to execute it.

Ex) If Driver version is 1.0.810.23316,

the name of file is "Osteosys_Exa3k_1.0.810.23316_release.exe"

(4) If Window7,

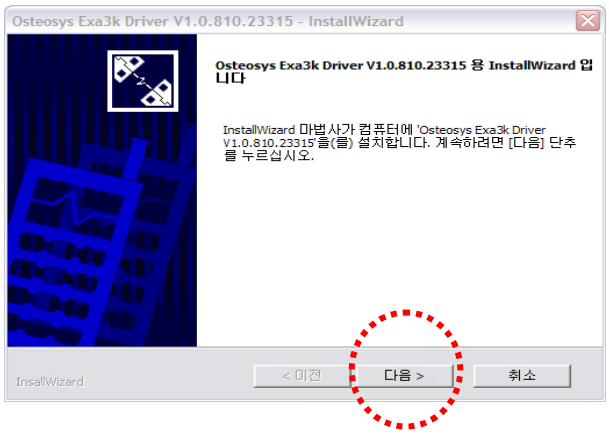
A. Move to "USB Driver\Window7" folder,

double click [Osteosys_E3K_versionNo_release.exe" to execute it.

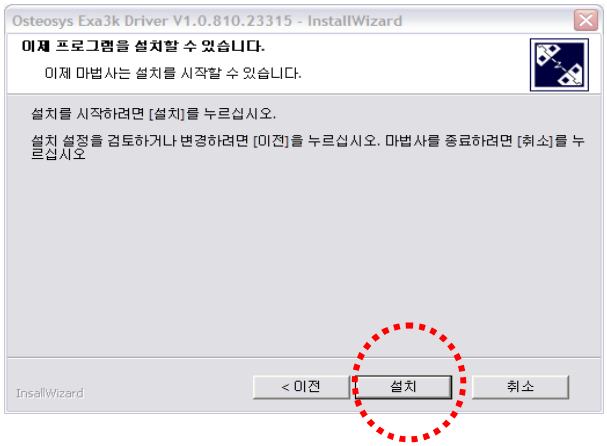
Ex) If Driver version is 1.1.1001.22233,

the name of file is "Osteosys_E3k_1.1.1001.22233_release.exe"

(5) Click "Next".


Osteosys Exa3k Driver V1.0.810.23315 - InstallWizard
Osteosys Exa3k Driver V1.0.810.23315 용 InstallWizard 입니다
InstallWizard 마법사가 컴퓨터에 'Osteosys Exa3k Driver V1.0.810.23315'을(를) 설치합니다. 계속하려면 [다음] 단추를 누르십시오.
InstallWizard
< 이전
다음 >
취소

(6) Click “Install”



(7) Completed installation USB Driver

3.2.3.1 Execution of Program and Configuration of the Incipient Environment

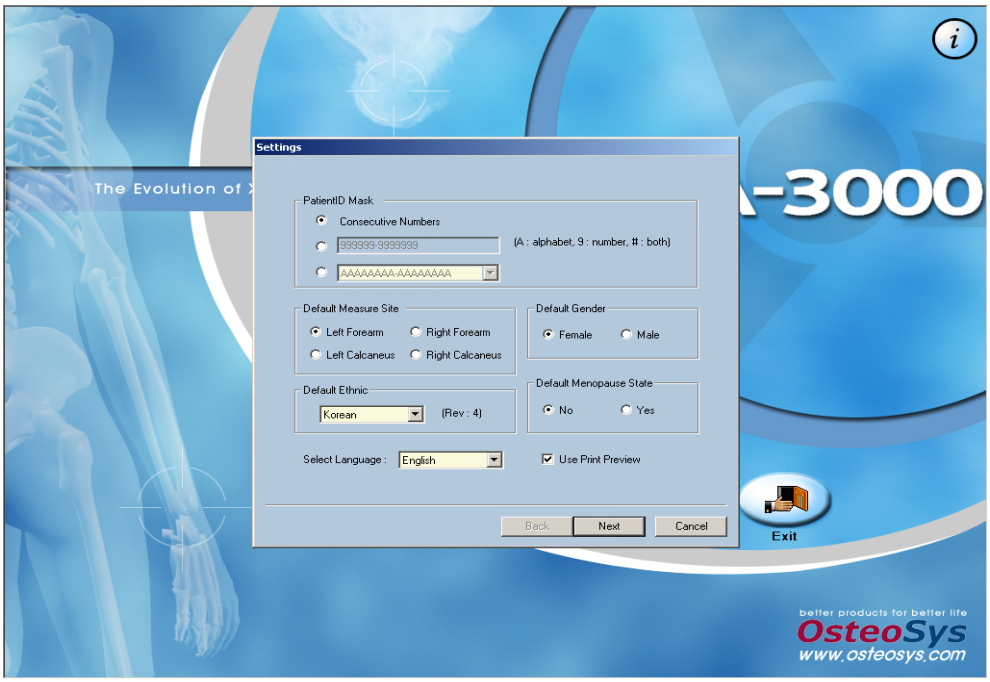
CAUTION !
If you hear any strange noise from the screen, switch it off and contact to OsteoSys or its authorized dealer.

(1) Press the power switch.

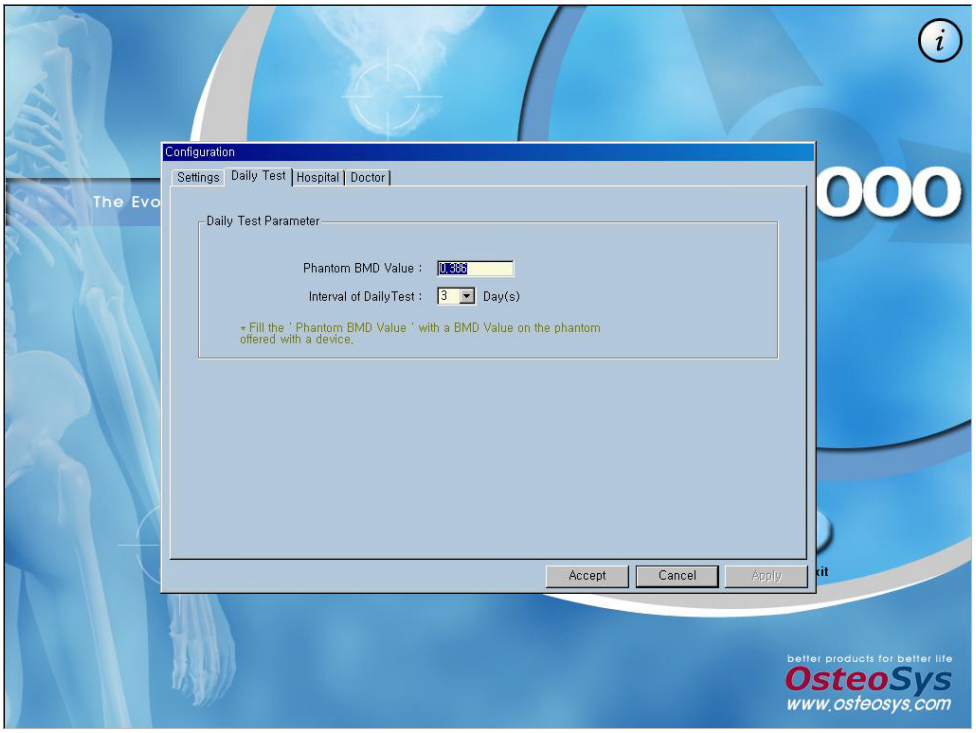
(2) 10 seconds after calibration that checks functions of the system and memory device, the program is automatically activated and you should configure the incipient environment.

(3) Settings :

- Patient ID Mask : Set the type of patients' ID.
- Default Measure Site : Set the default measurement part of the body.
- Default Gender : Set the default patient's gender.
- Default Ethnic : Set the default patient's race.
- Default Menopause State : Set the default patient's menopause state.
- Select Language : Select your own language to use the program.
- Use Print Preview : Select the function "Print Preview" or not.



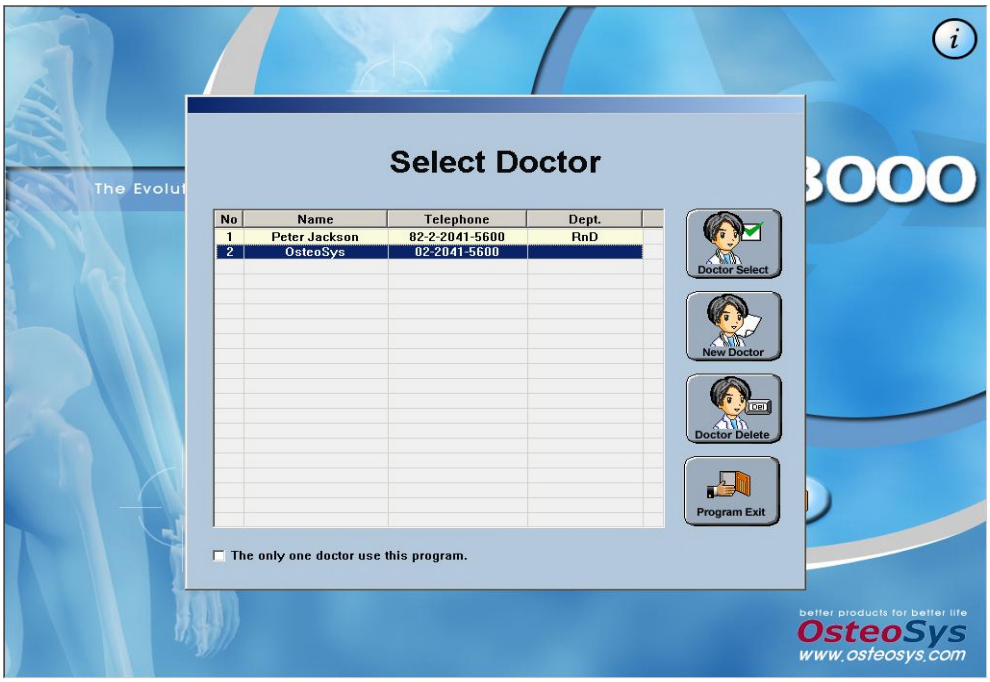
(4) Calibration : Set the BMD value of the QC phantom. Phantom BMD value should be the BMD values of QC phantoms, which is included in the list of accessory. The period of Daily test could be 3 days for the maximum.



(5) Hospital : Set the name, address and phone number of your hospital.

3.2.3.2 Registration & Deletion of Users

(1) As soon as you configure the user environment, the “Select Doctor” window appears as shown below. If you are a registered user(doctor), click the “Select Doctor” button after selecting your name in the “Select Doctor” window using the mouse. And then if you enter the password in the edit box “Enter Password” and click the “OK” button, you can log in the program.



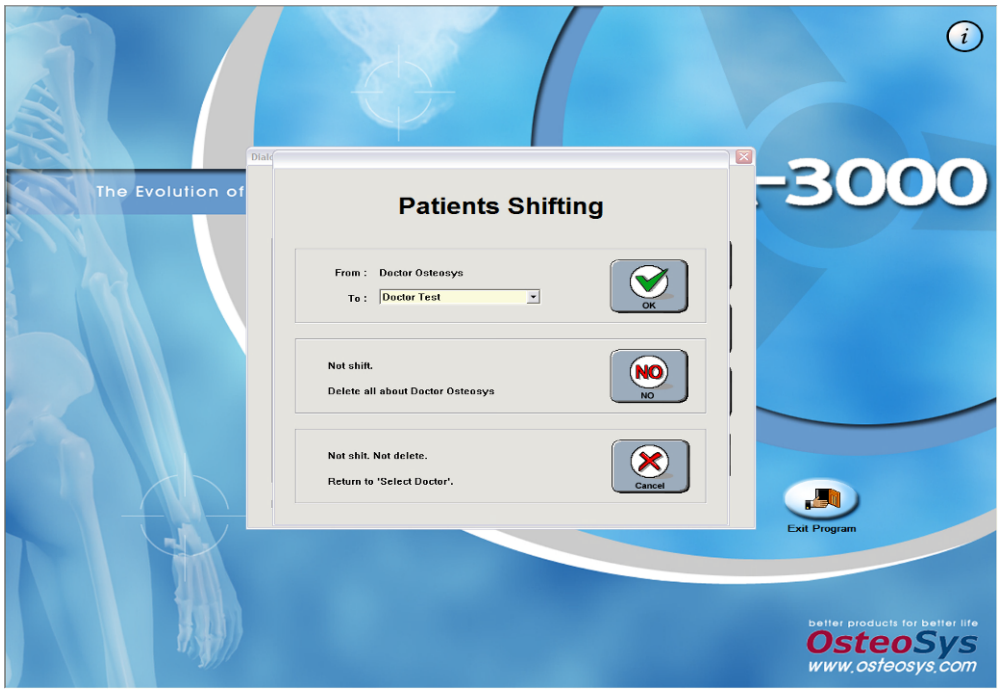
(2) If you are a new user(doctor), click the “New Doctor” button in the “Select Doctor” window, and then the “New Doctor” window appears. If you enter your information(name, phone number, department and password) and click the “OK” button, the registration process is completed. The log-in process is same as the description “(1)”

(3) If you want to delete registered users, select a desired user and click the “Delete Doctor” button of the “Select Doctor” window. If there are two or more registered users, the message box “Move Patients?” inquiring your intention appears as shown below.

- “OK” : All registered users, except the user you selected to delete, are displayed on the left side of this “OK” button.. If you select the user who you want to move the patients’ data(the user you selected to delete has measured until now) to and click this button, the data moves to the selected user’s DB and the user(you selected to delete) is deleted

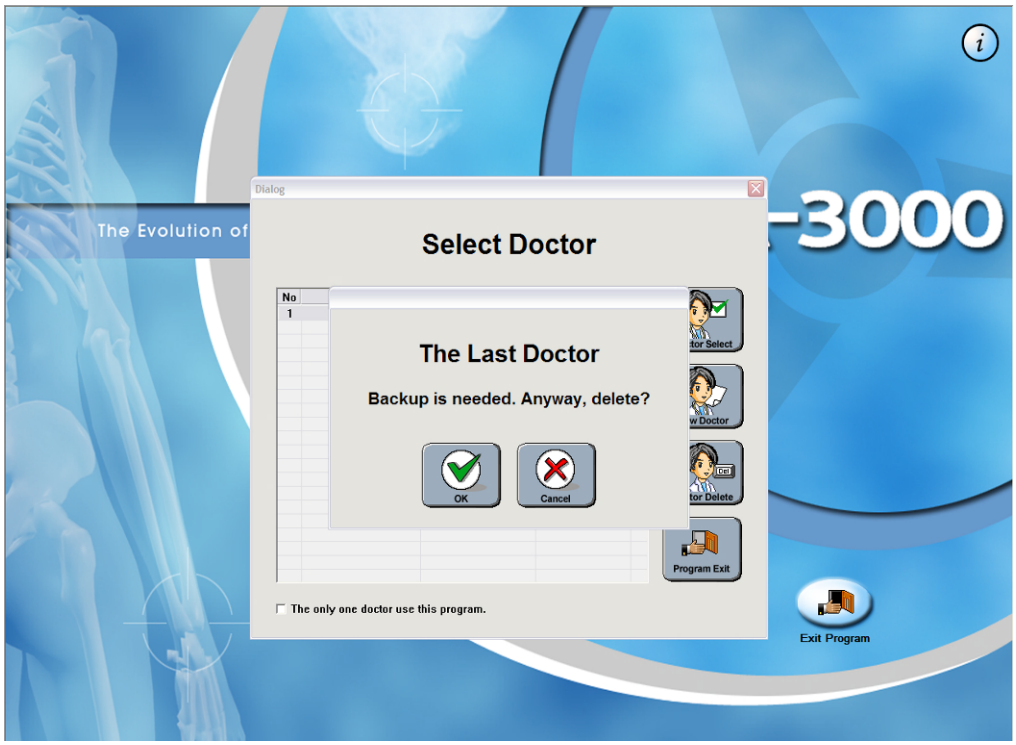
- “NO” : If you click this button, the user you want to delete and the patients’ data (the user you selected to delete has measured until now) are deleted

- “Cancel” : If you click this button, you can cancel the deletion process.



(4) If you click the “OK” or “NO” button, the message box “Really Delete Doctor?” inquiring whether to delete the user surely appears. If you click the “OK” button, the user information is deleted. And if you click the “Cancel” button, you could cancel the deletion

(5) If there is only one registered user when you click the “Delete Doctor” button in the “Select Doctor” windows, the message box “Last Doctor !!” inquiring to advise data backup and to delete the user surely appears. If you click the “OK” button the deletion process starts.

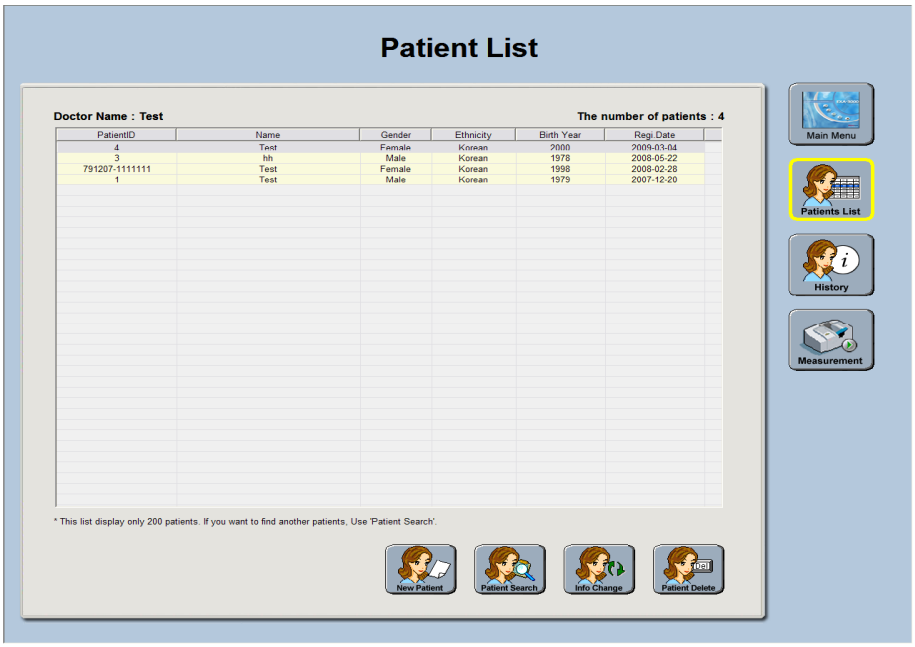


(6) If you are only one user, check the checkbox “The only one doctor use this program” on the bottom of the “Select Doctor” window. Then you can use the system without entering password.

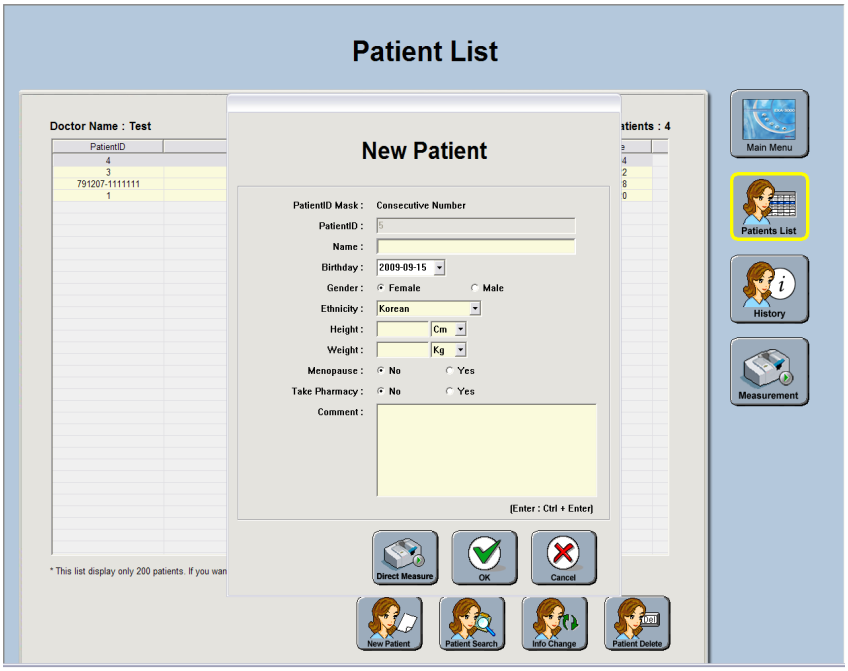
3.2.3.3 BMD Measurement

< Registration & Retrieval of Patients >

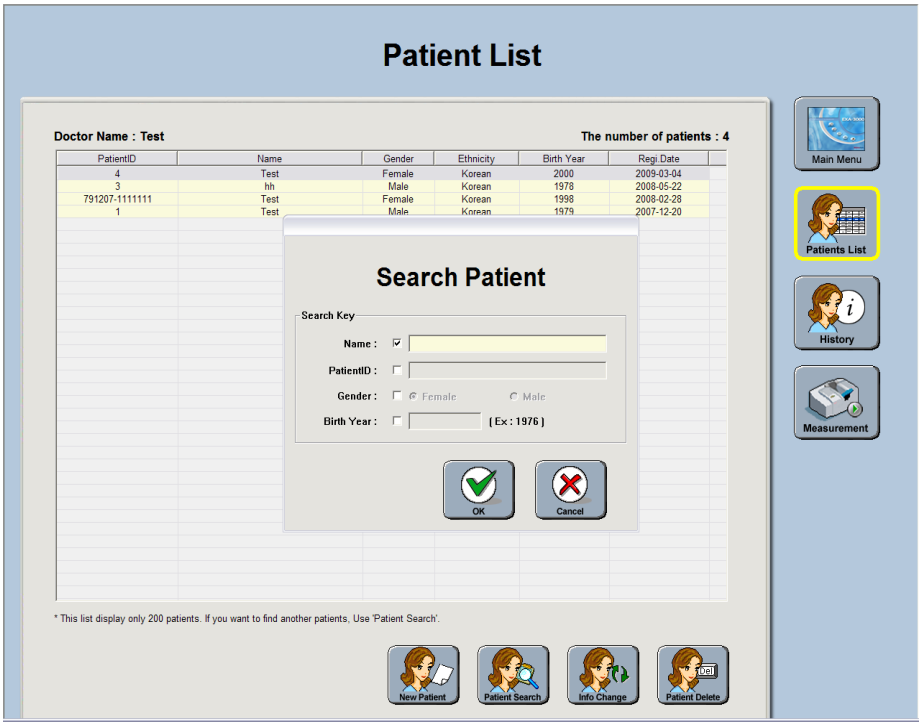
(1) If you click the “BMD Measurement” button in the default screen, you can move to the “Patient List” screen contains all information of registered patients.



(2) If you want to register new patients, click the “New Patient” button on the bottom of the “Patient List” screen. Then the “New patient” window you can enter the information of new patients appears. Enter the information and click the “OK button”. Then the patient is registered and the information is displayed.

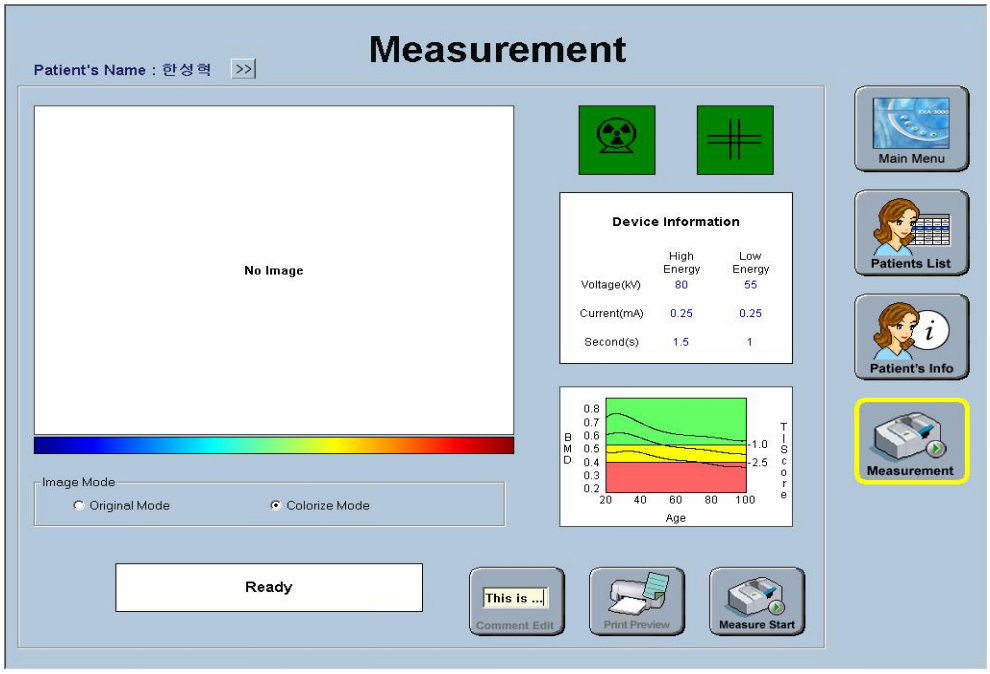


(3) If you want to retrieve registered patients, click the “Patient Search” button, and then the “Search Patient” window contains the retrieval items(name, ID, gender and date of measurement) appears. If you enter the desired patients’ information and click the “OK button, then the results appears in the screen.

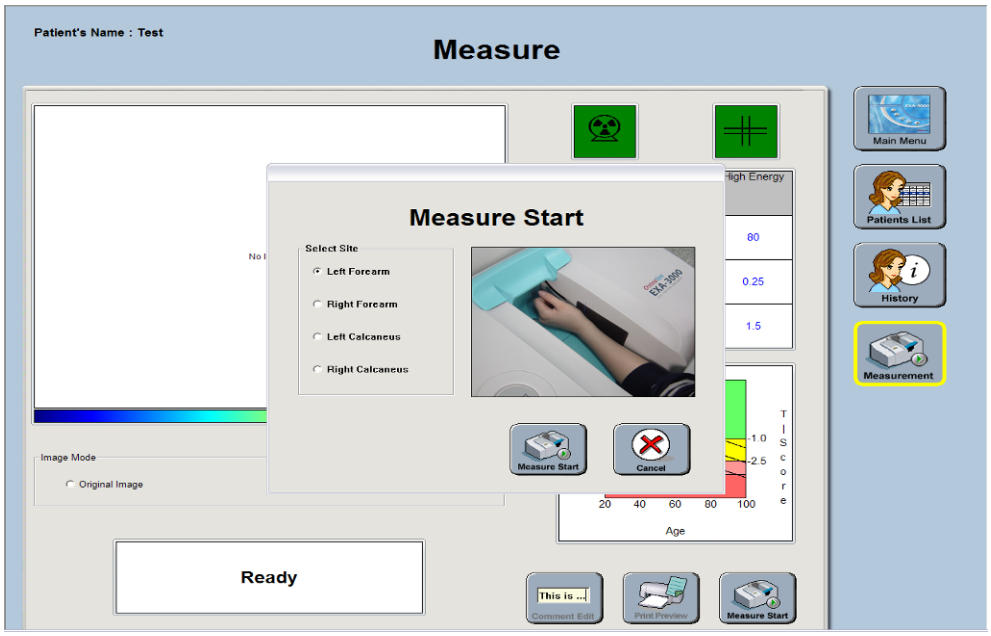


< Measurement of Patients >

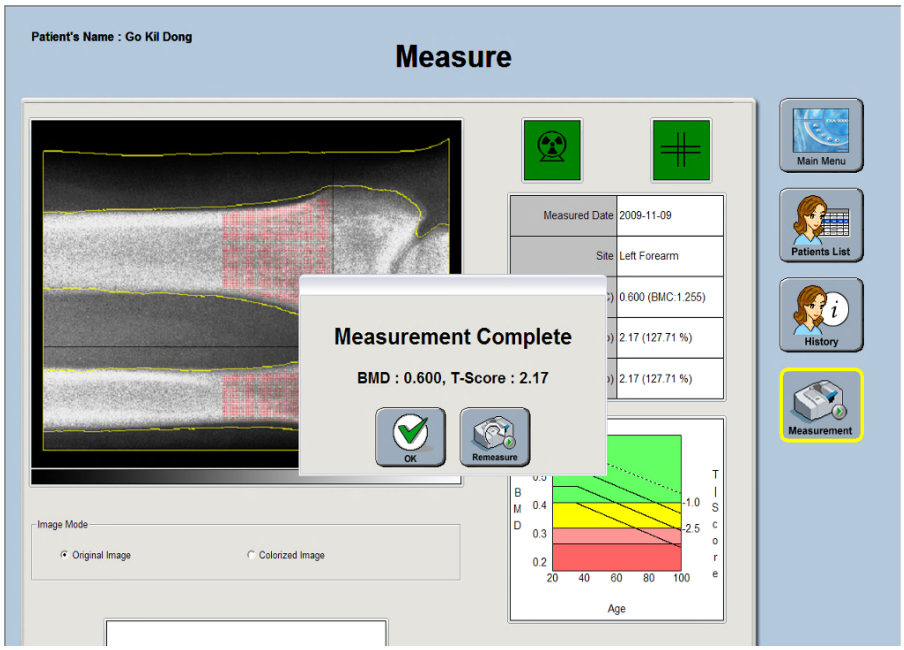
(1) If you want to measure BMD, select a desired patient using the mouse in the "Patient List" screen and click the "Measurement" button on the right side of the screen. Then the "Measurement" screen appears as shown below.



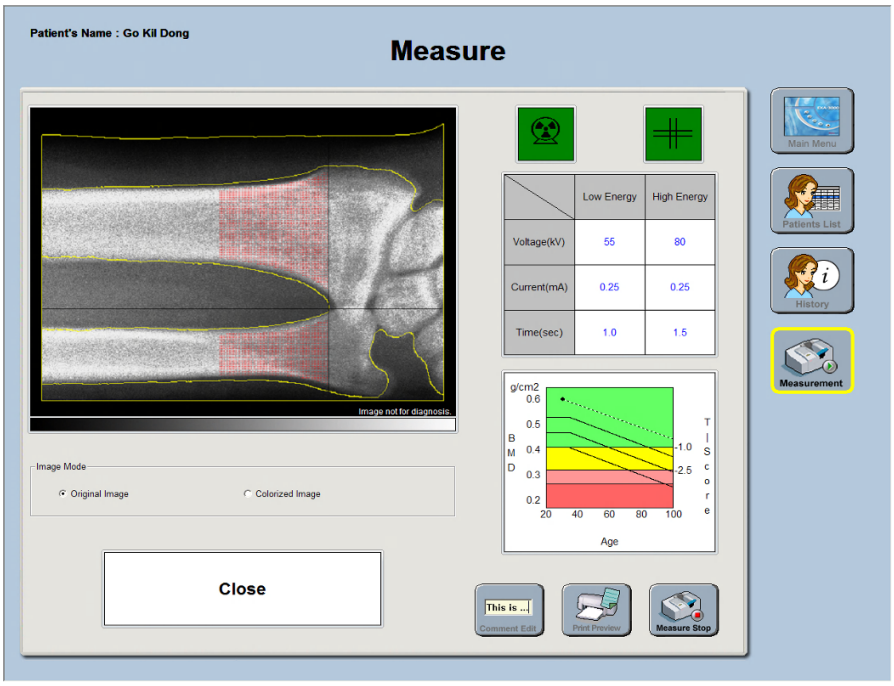
(2) Click the "Measure Start" button on the bottom of the "Measurement" screen. Then the message box "Measure Start" inquiring measuring parts of the body appears. If you select measuring parts and click the "Measure Start" button, X-ray radiates from the X-ray source.



(3) When X-ray radiates, the word on the “Measure Start” button is changed into “Measure Stop”. In case of emergency, click this button. Then X-ray radiation stops. In the normal condition, the message box “Measurement Complete !!” inquiring about whether to restart to measure BMD or not appears with an alarm sound after BMD Measurement being finished.



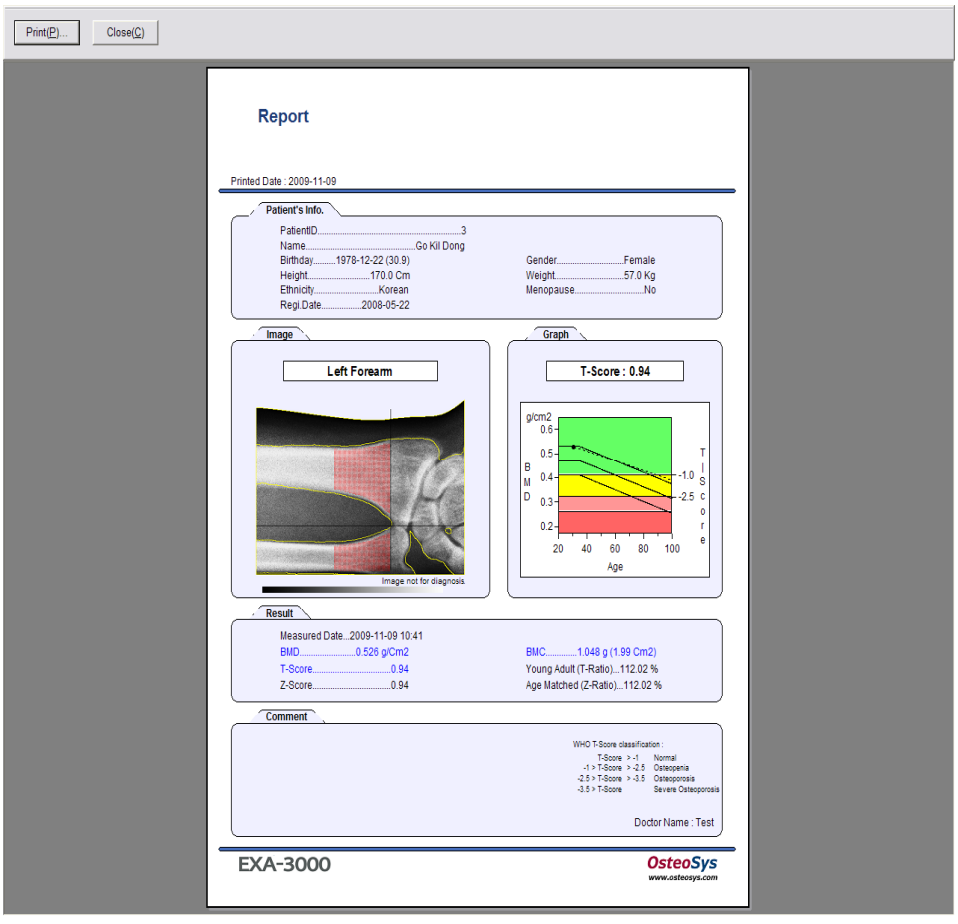
(4) If you click the “OK” button, the results of X-ray appears in the screen as shown below, on the contrary, if you click the “Remeasure” button, you can restart to measure BMD.



CAUTION !
When you hear the alarm sound, you should let a patient put his arm(or foot) out of the device. Even if there is no sound caused by some trouble in the system, after clicking the “Start Measure” button., you should let a patient put his arm(or foot) about 5 seconds after.

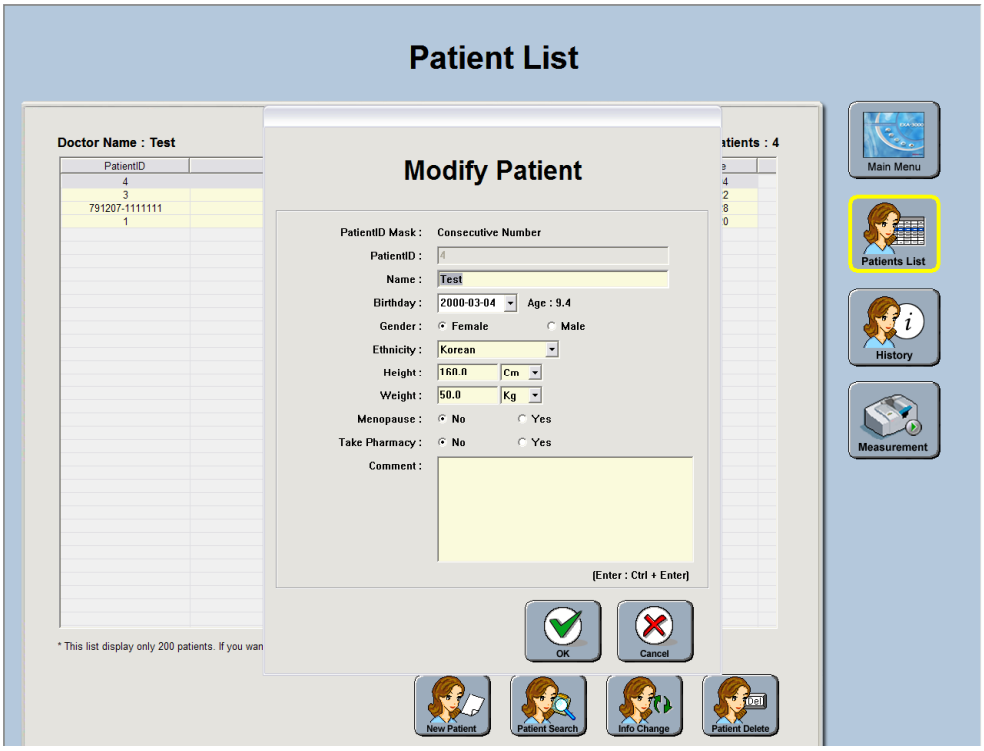
(5) If you click the “Print Preview” button on the bottom of the screen that shows the results after measuring BMD, you can see the results that will be printed out in advance as shown below. If you click the “Print” button on the top of this screen, the results is printed out. The “Print Preview” function can be set in the “Configuration” menu.

3.2.3.8 Configuration of Environment



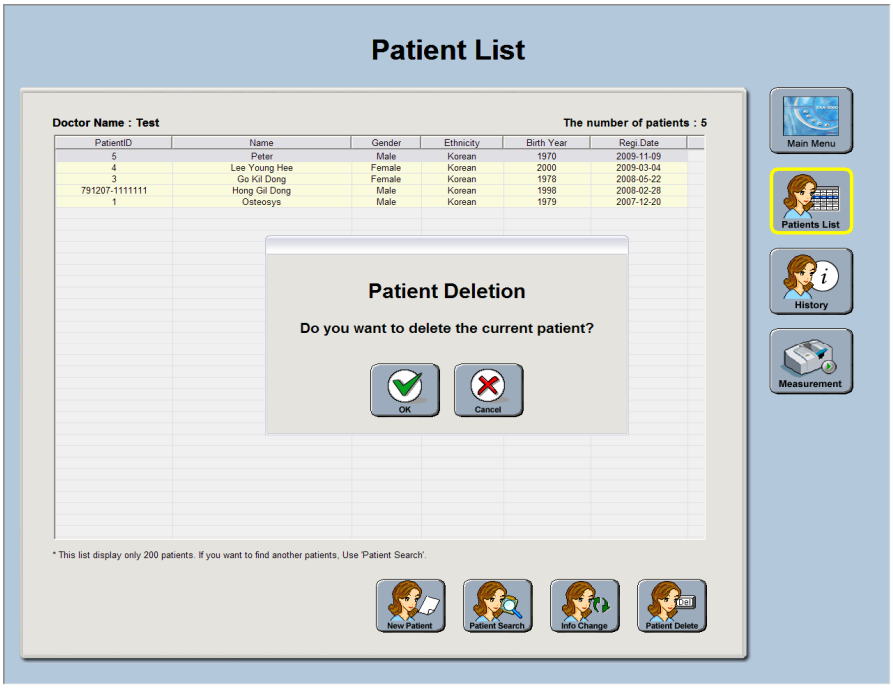
3.2.3.4 Revision & Deletion of Patient's Information

(1) If you want to revise the registered patients' information, select a desired patient using the mouse and click the "Info Change" button in the "Patient List" screen. Then the "Modify Patient" screen appears, in this condition, if you enter a new value to make desired changes in the patient's information and click the "OK" button, the patient's information is revised.



(2) If you want to delete the registered patients' information, select a desired patient using the mouse in the "Patient List" screen. You can select several patients at the same time. To do so, click those patients while pressing the Ctrl key or if you want to select all patients within certain, click the first and the last line of the area while pressing the Shift key.

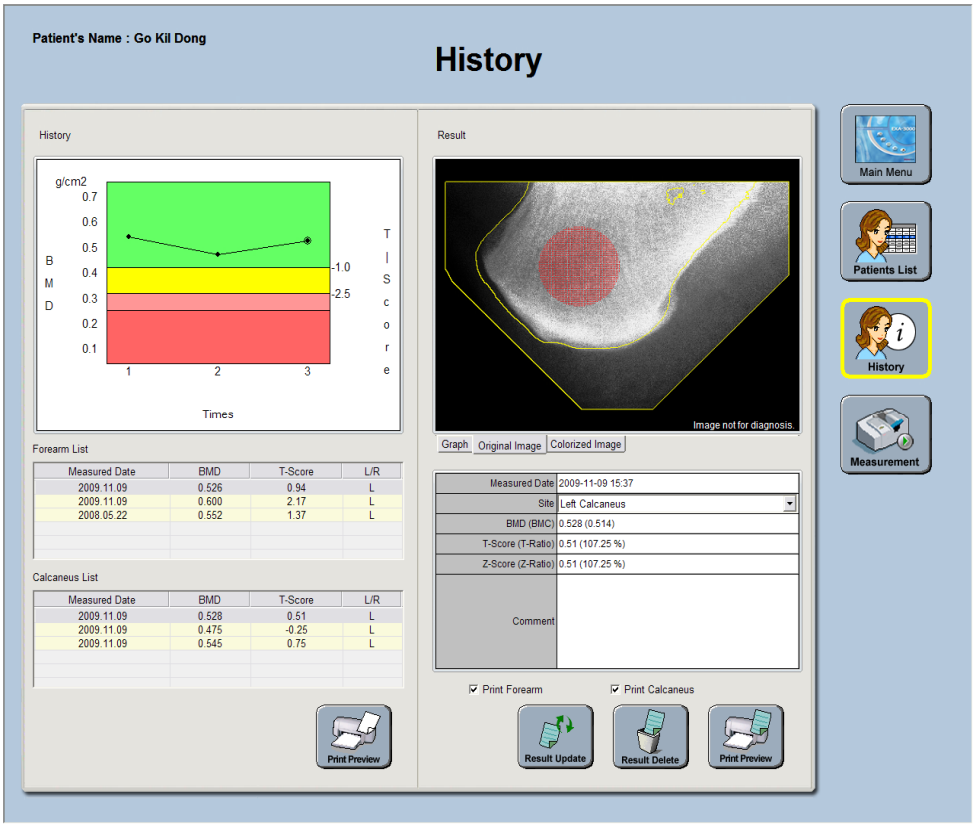
(3) After selecting a desired patient, click the “Patient Deletion” button on the bottom of the screen. Then the message box “Patient Deletion” inquiring about whether to delete the information surely appears and if you click the “OK” button, the information is deleted.



3.2.3.5 Inquiry & Deletion of Clinical History of Existing Patients

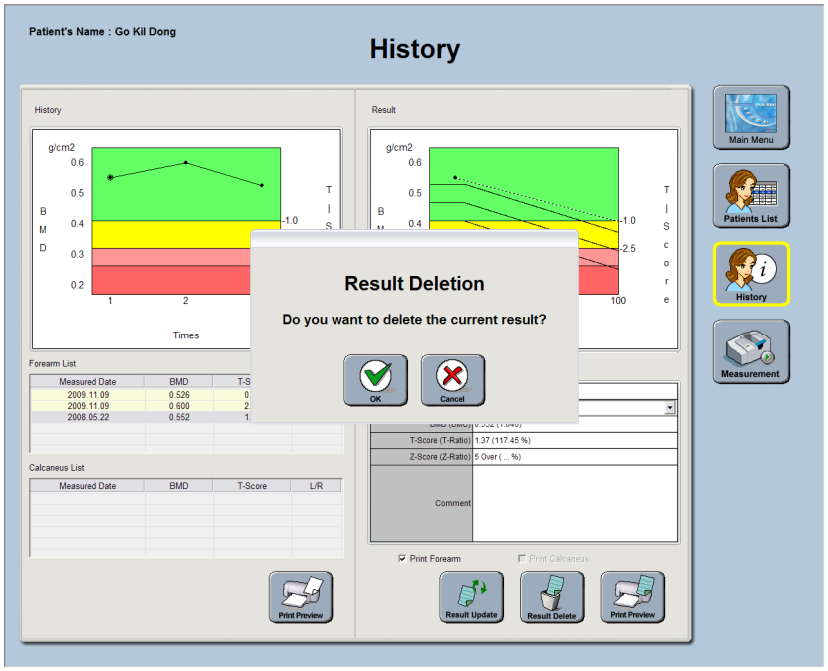
(1) If you want to retrieve the clinical history, select a desired patient and click the “Patient’s Info” button on the right side of the “Patient List” screen. Then “Patient Info.” screen appears that contains the patient’s clinical history.

(2) On the left & below side, the measurement results list shows. If you select a measurement result in the list, the relevant data(image, BMD value, date, graph, etc.) appears. If you check the two check box(“Print Forearm” & “Print Calcaneus”) next to the list, you can select whether to print the results for each.



(3) In this condition, you can measure BMD again. Click the “Measurement” button on the right side for each. You can execute them in the same way as described in “**3.2.3.3 BMD Measurement < Measurement of Patients >**”

(4) If you want to delete the clinical history of patients, select a desired history and click the button “Result Delete” in the “Patient List” screen. Then the message box “Result Delete” that inquiring about whether to delete the history or not appears. If you click the “OK” button, the history is deleted.



(5) After revising patients’ information(scan site and comment), if you click the “Result Update” button in the result screen, the message box “Result Update” inquiring about whether to update the information surely appears. If you click the “OK” button, the relevant history is updated.

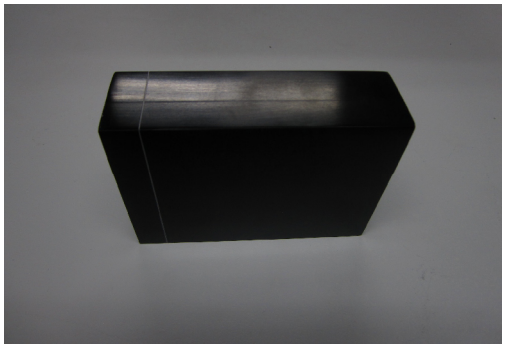
3.2.3.6 Calibration of EXA-3000

(1) To operate Calibration, put QC Phantom inside of the slot. At that time, please push Heel Positioner to the end as if you measure the forearem to place QC Phantom well.

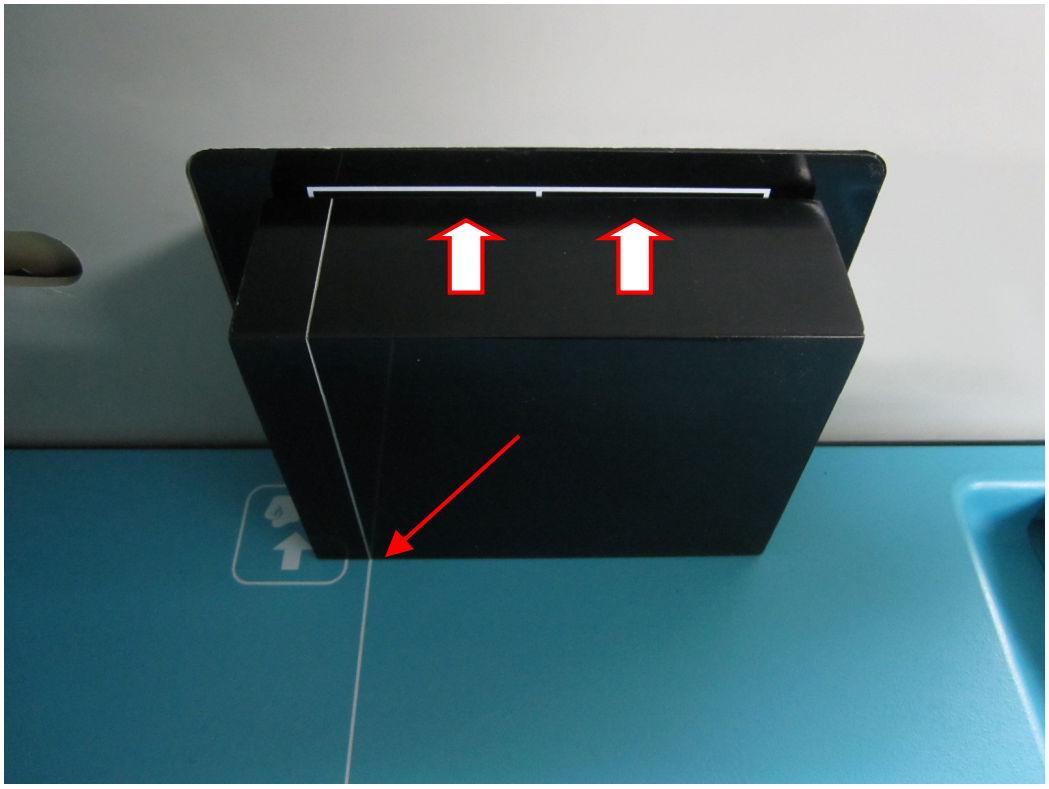
(2) There is the white line on QC Phantom. Please fit the white line on QC Phantom with the line on the Positioner, and press on the right side, the detector.

 # Caution

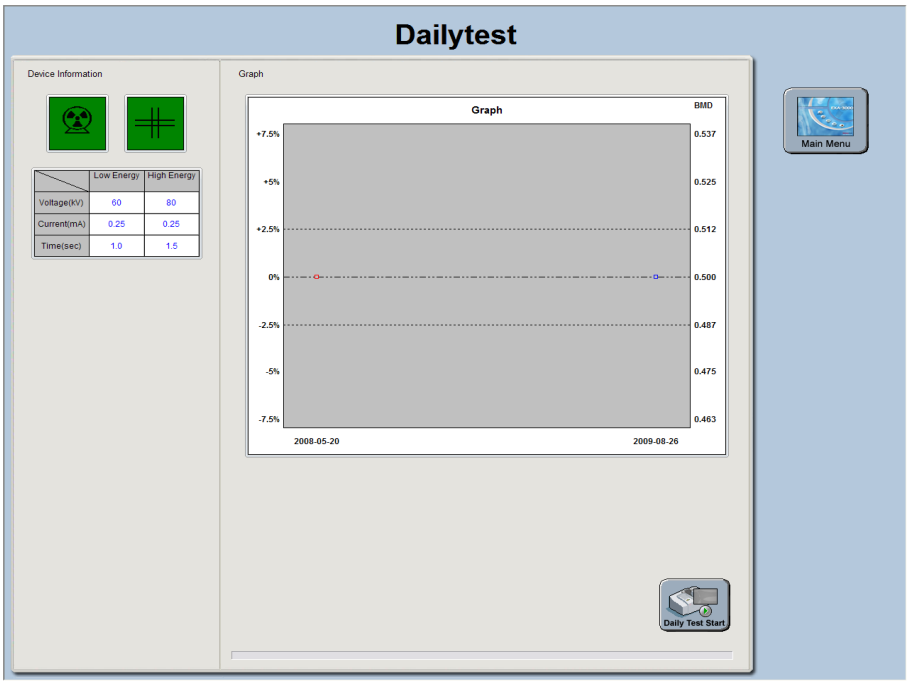
Do not use this phantom for measurement (Only Daily Test)



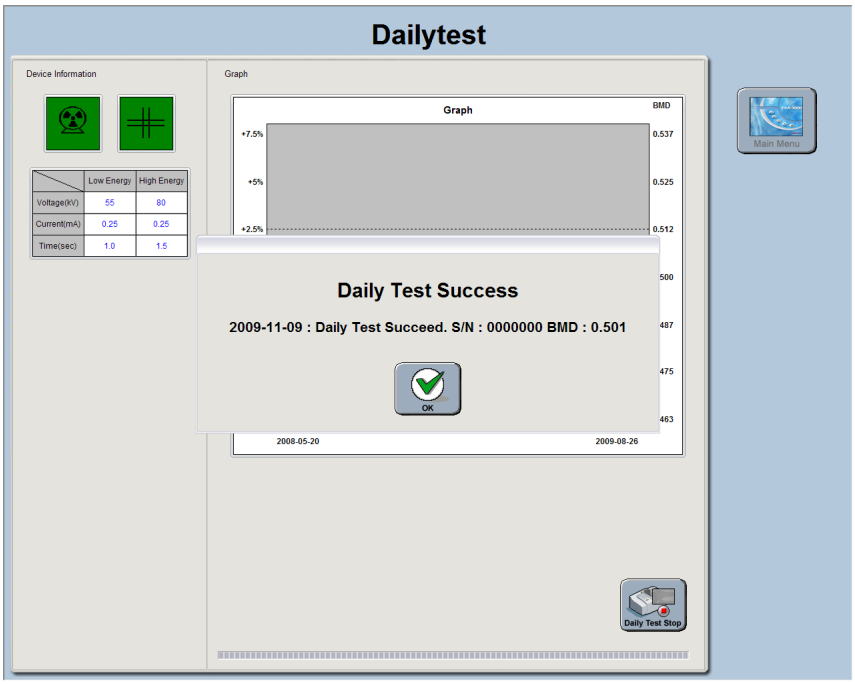
< QC Phantom >



(3) To execute “Daily Test” the system, click the “Daily Test” button in the default screen. Then the “Daily Test” screen appears. When you click the “Daily Test Start” button in this screen, X-ray radiates from the X-ray source.



(4) When X-ray radiates, the word on the “Daily Test Start” button is changed into “Daily Test Stop”. In case of emergency, click this button and if you click the button, X-ray radiation stops. In the normal condition, the message box “Daily Test Success” appears as shown below with an alarm sound after progressing “Daily Test” and if you click the “OK” button, results of calibration are appeared.



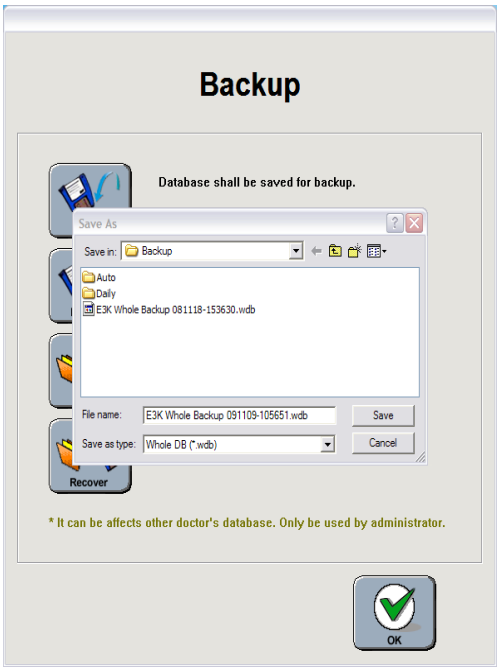
Whenever you execute “Daily Test” or “Calibration”, you should use the QC Phantom included in the accessories list. And you should set the BMD value of the QC Phantom on the “Configuration” menu.

3.2.3.8 Configuration of Environment

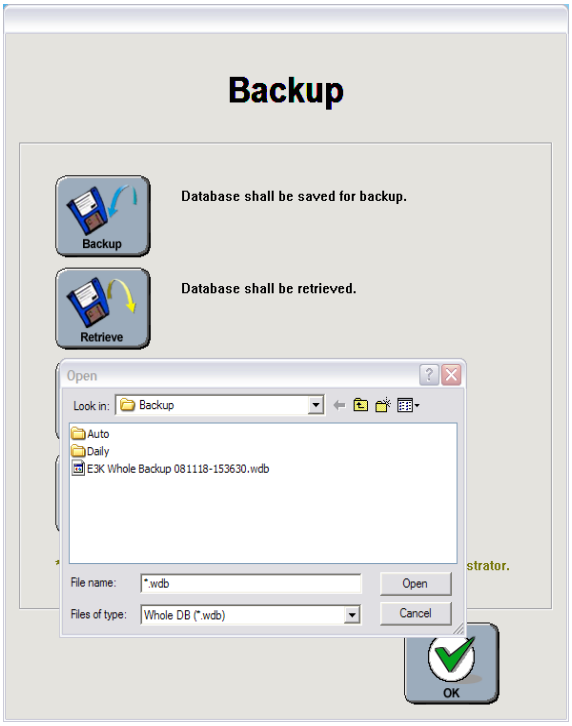
3.2.3.7 Data Backup

If you need to save the data, click the “Backup” button in the default screen. If you click the button, the default screen of “Backup” menu appears as shown below.

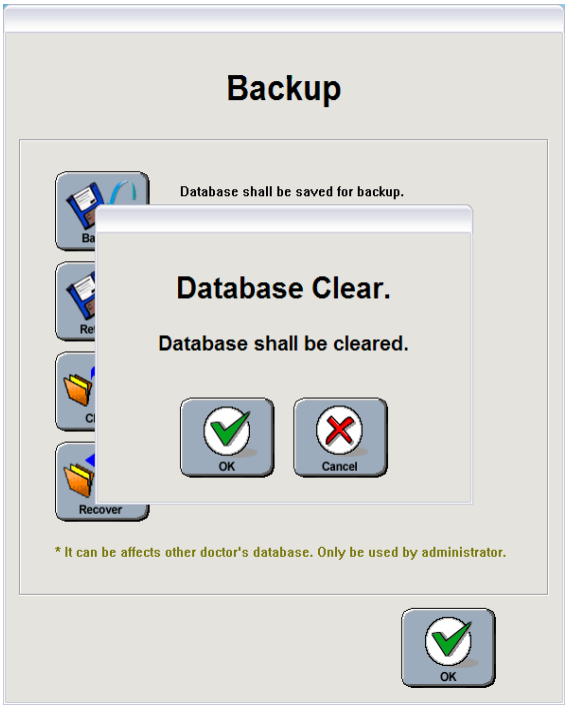
(1) Backup : If you click this button, you can save all users’ DB in the PC.



(2) Retrieve : If you click this button, you can exchange all users' DB into others in the PC.



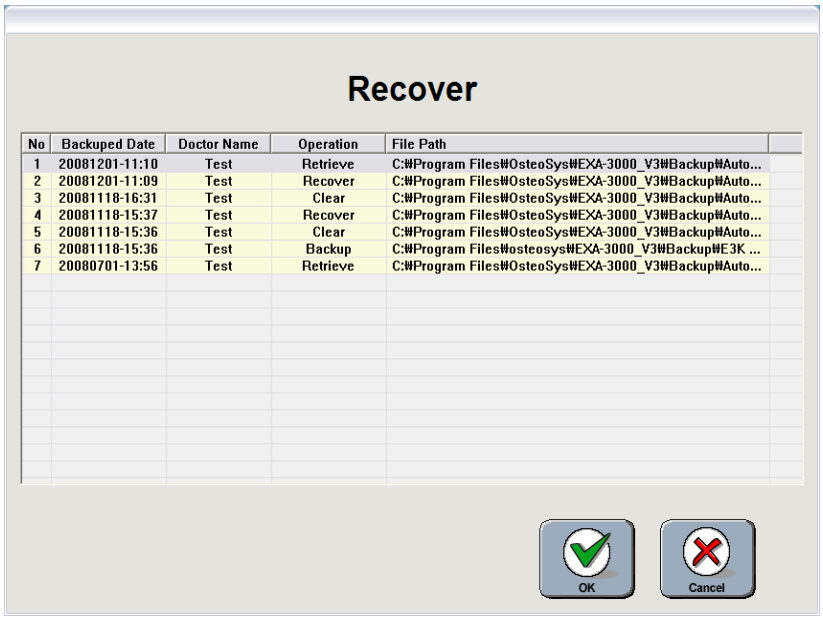
(3) Clear : If you click this button, the message box "Surely clear doctor?" inquiring whether to delete the user surely appears. If you click the "OK" button, you can clear all users' DB.



(4) Recover : If you click this button, you can recover all users' DB.

All records related the DB are written in this field.

After selecting the record and clicking the "OK" button in this screen, the DB is recovered.



3.2.3.8 Configuration of Environment

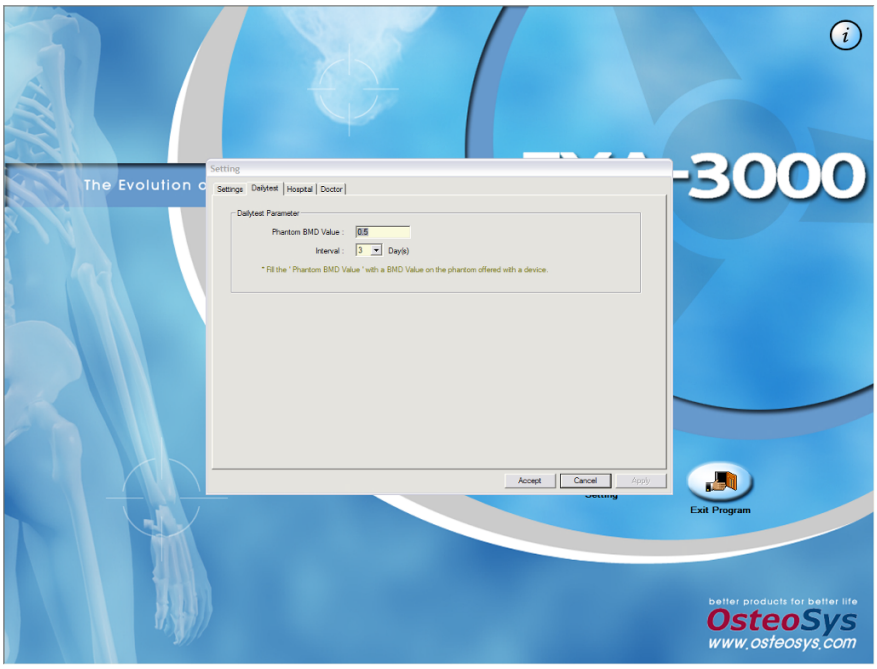
(1) If you want to configure the user environment again, click the “Configuration” button in the default screen. There are four items from “Settings” to “Doctor” in this menu.

(2) Settings :

3.3.2.1 Execution of Program and Configuration of the Incipient Environment

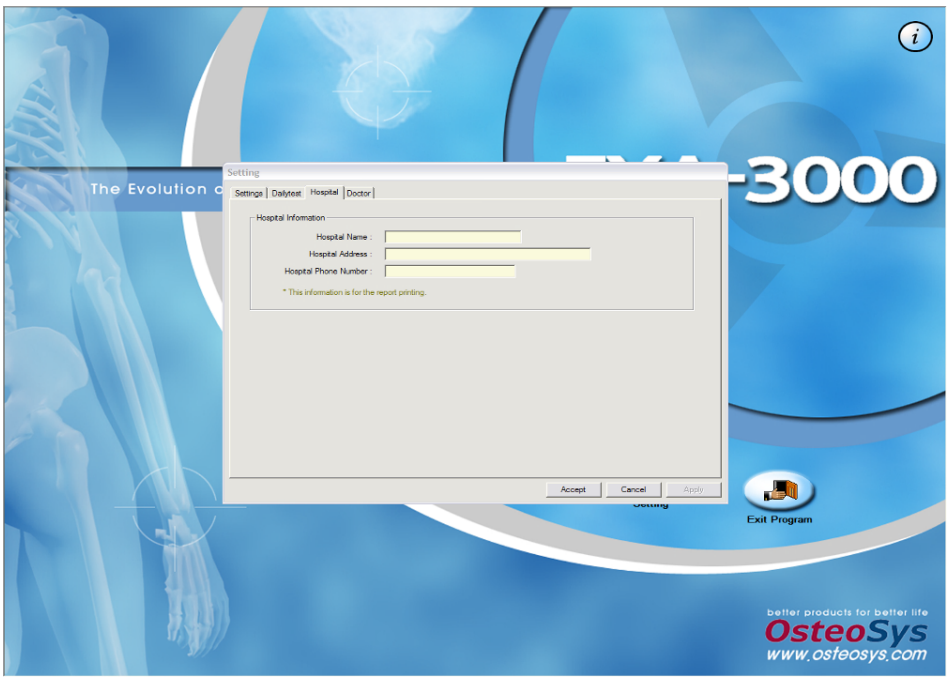
(3) Calibration :

3.2.3.1 Execution of Program and Configuration of the Incipient Environment



(4) Hospital :

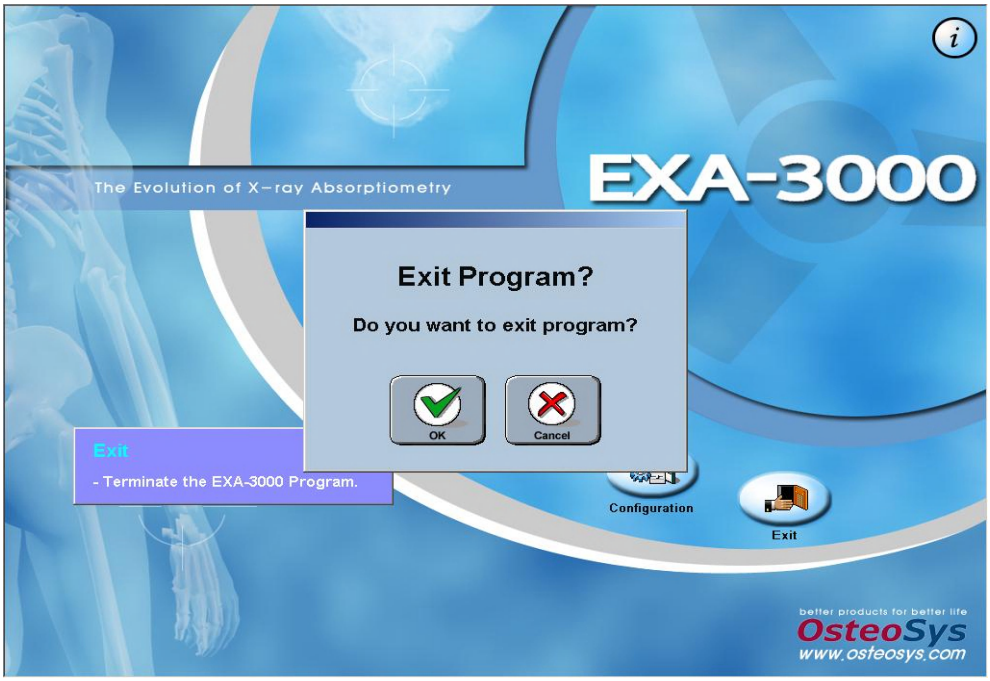
3.2.3.1 Execution of Program and Configuration of the Incipient Environment



(5) Doctor : You can set your name, phone number and department. If you click the "Change PW" button, you can change your password.

3.2.3.9 Inactivation of EXA-3000

If you click the "**Exit**" button in the default screen, the message box "Exit Program?" inquiring about whether to exit the program appears and if you click the **"Ok"** button, the program is inactivated.



Chapter 4. Maintenance and Repair of EXA-3000

4.1 Resolution to Problems

4.2 Maintenance and Repair

4.2.1 Cleaning

4.2.2 Stockpile and Replacement of Articles

4.2.3 Storage

4.3 Safe Use of EXA-3000

4.3.1 Safety Rules

4.3.2 Cautions Related to Use of Electronic Medical Equipment

4.1 Resolution to Problems

If EXA-3000 shows following symptoms, check the system as follows.

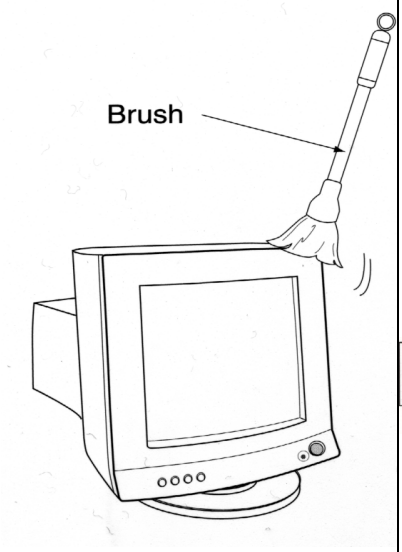
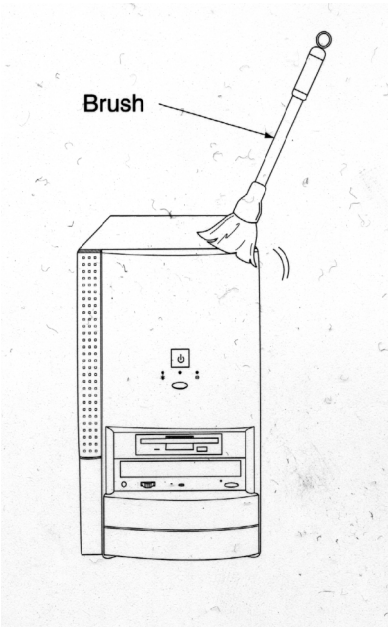
Problems	Checking points
EXA-3000 is not activated with the power on.	Is the device properly plugged?
	Isn't the power cord damaged?
	Aren't the fuses gone?
Computer is not activated with the power on.	Is the device properly plugged?
	Isn't the power cord damaged?
Monitor is not activated with the power of the computer on.	Is the monitor switched on? User's instructions of monitor
Screen of the monitor is not bright enough.	Adjust brightness. User's instructions of monitor
Result of calibration of the system turns out to be abnormal.	3.2.2.6 Calibration of EXA-3000
Result of measurement turns out to be abnormal	3.2.2.2 BMD Measurement 3.2.2.6 Calibration of EXA-3000
Despite measurement according to the instructions, its result turns out to be abnormal	Is the desired part of the body properly placed?
	Hasn't the system been calibrated for long? 3.2.2.6 Calibration of EXA-3000

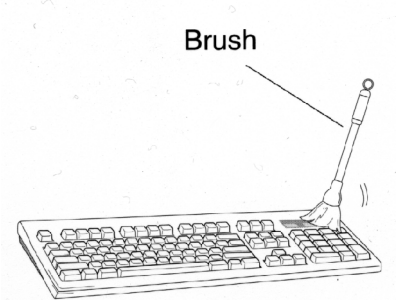
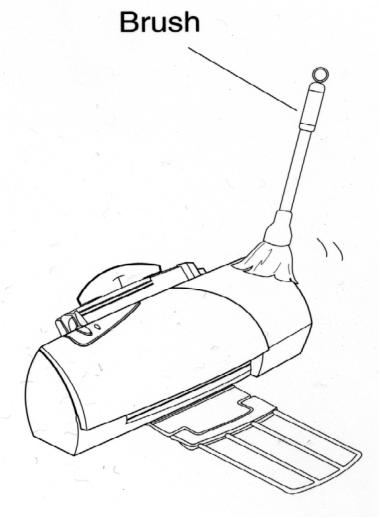
CAUTION !
If you cannot resolve the problem contact to OsteoSys or its authorized dealer.

4.2 Maintenance and Repair

4.2.1 Cleaning

CAUTION !
Turn off the power before cleaning the product.

Product	Example	Instructions
Monitor		Dust the monitor with a soft brush every day. Clean the screen of the monitor with a soft cloth. If there is a strong stain on the cover, soak a clean and soft cloth with neutral detergent diluted with water in about a ratio of 5 to 1, and dry the cloth and remove the stain with it. And then wipe out the stained area with soft and dry cloth again. Make sure not to put water or detergent on the monitor directly. Water or detergent can damage the monitor. If you use volatile chemicals such as benzene or thinner, surface of the monitor can be damaged.
Computer		Dust the computer with a soft brush everyday. If there is too much dirt on the computer, soak a clean and soft cloth with neutral detergent diluted with water in about a ratio of 5 to 1, and wring water from the cloth and wipe out dust. Make sure not to put water or detergent on the computer directly. Water or detergent can damage the computer. Make sure not to use volatile chemicals such as benzene or thinner because it can damage the surface of main body of the computer.

Product	Example	Instructions
Keyboard		Dust the keyboard with a soft brush. Direct contact with water or detergent can damage the keyboard.
Printer		Remove paper from the printer and dust the printer with a soft brush carefully. If there is strong stain on the printer, soak a clean and soft cloth with neutral detergent diluted with water in about a ratio of 5 to 1, and wring water from the cloth and wipe out dust. And then clean the stained area with dry cloth. Cover the printer with printer cover to avoid water. **User's instructions for printer**
Device		(Cleaning) - Unplug the product and dust the device with a soft brush carefully. (Disinfection) - The Hand Guide and Supporter which the patient touches should be cleaned by wiping the part with a water wringed clean and soft cloth soaked with neutral detergent diluted in water with a ratio of 5 or 6 to 1. After this procedure clean the stained area with a dry piece of cloth. Make sure not to put water or detergent on the device directly because it can cause fatal damage in the electric circuit contained inside.

4.2.2 Stockpile and Replacement of Articles

Make sure to keep following articles of consumption all the time.

2.1.5 Articles List

Articles	Specifications
Printing paper	Use white A4 paper. Refer to user's instructions for details.
Ink cartridge	Replace ink cartridge with a new cartridge if the printed text or picture is not vivid enough. **User's Instructions for Printer**

4.2.3 Storage

Daily storage	1) Unplug the power cord. 2) Dust on the product can damage the system. After use, make sure to cover it with vinyl cover. **4.2.1 Cleaning**
Storage for a long time of period	1) Unplug the power cord. 2) Do not detach cable of the device connected to plug to prevent dust from coming inside. Place cable near the product or at an empty area in its front. 3) Put cover on the product to avoid dust. 4) Keep the product according to instructions described in **"2.2 Installation of EXA-3000"** **2.2 Installation of EXA-3000**

4.3 Safe Use of EXA-3000

4.3.1 Safety Rules

The followings are instructions for safe use of the product
Make sure to comply with the instructions when you activate the system.
Refer to "4.3.2 Caution related to electronic medical equipment"

4.3.2 Cautions Related to Use of Electronic Medical Equipment

CAUTION !	➢ Do not open it because there are some high-tension components inside. It might cause serious danger. ➢ Check if the cable coating is not damaged before turning on the system to prevent electric shock or leakage of electricity. If it is damaged or broken, immediately contact an agency. ➢ Do not share the power outlet with other products. If you share the outlet it will affect the product.
CAUTION !	➢ Read user's instructions carefully before using the product. ➢ Place the user's instructions at a designated place so that users can read it anytime they need it. ➢ If you hear a strange noise or if you find any abnormality on the screen after turning on the product, contact the headquarters or an agency. ➢ Make sure to turn off the power switch before cleaning the product.

4.3.2 Cautions Related to Use Electronic Medical Equipment

Safety rules described below are based on Paragraphs 495 of laws and ordinances promulgated by Ministry of Welfare of Japan. The safety rules pertain to use of electric medical equipment. Read them carefully for safe use of the product and make sure to refer to **"4.3.1 Safety rules"**

4.3.1 Safety Rules

1 **Nobody can handle EXA-3000 except for doctors and authorized personnel**

2 **Comply with followings in times of installation of EXA-3000. Do not install it in following places.**

A) Places where the product is exposed to water vapor
B) Places where the product is exposed to spray or splashing water.
C) Places where the product is exposed to high density oil vapor
D) Places where the product is subject to excessive shocks or vibrations.
E) Places where the angle of inclination of the mounting surface exceeds 10 degrees.
F) Places where air pressure, temperature or humidity drastically changes.
G) Places exposed to direct sunlight or places where air is polluted due to dirt, salt and sulfur
H) Places where chemicals are kept or toxic gas is leaked.
I) Places where the AC power line voltage fluctuates heavily
J) Places where the AC power line voltage fluctuates heavily while this product is operating.
K) Places where there is a ventilation problem.
L) Do not lean, shake or rock the product during transportation.
M) Adjust frequency, voltage or current to the product.
N) The product is portable but make sure to put a brake on it when you stop the product.
O) Ground the product by using ground wire.
P) Do not share the power outlet.

3 **Check followings before using the product.**

A) Whether power is off before putting a plug in the socket.

B) Whether the power supply line is suitable with that of the system (AC 100~240 V)

C) Whether the system is fully grounded.

D) Whether all the connection parts(power and optional equipment) are connected with the system properly.

2.4 Before Turning on Power

E) The product has been factory-set for optimum performance. Do not attempt to adjust any preset controls or switches except for operation as specified in this manual.

F) If you experience any trouble with the product, turn it off immediately and contact OsteoSys or its authorized dealer for assistance.

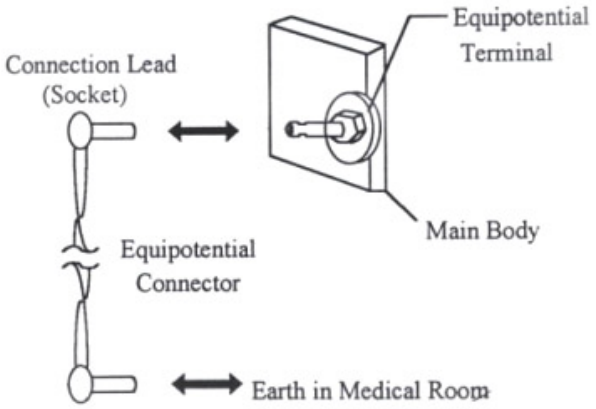
G) Before electrically or mechanically connection any other manufactures' devices to EXA-3000, contact OsteoSys or its authorized dealer for instructions

H) Do not operate the product improperly when you use it with other products.

I) Make sure to check whether external parts of the device directly touch the patient.

J) Make sure to check whether the products keep distances at least 10cm from walls.

CAUTION !
Equipotential Bonding In hospital, doctors and patients are subjected to dangerous, uncontrollable compensating currents. These currents are due to the potential differences between connected equipment and touchable conducting parts as found in medical rooms. The safest solution to the problem is accomplished is consistent equipotential bonding. Medical equipment is connected with connecting leads made up with angle sockets to the equipotential bonding network in medical rooms.



NOTE !
Try to place the system far from power generators, X-ray machines, broadcasting stations, and transmission lines to avoid electrical noise during scanning. Otherwise, abnormal images may result. An independent circuit and safely grounded outlets are strongly recommended for EXA-3000. Poor or abnormal images may occur if the system shares a power source with other electrical or electronic equipment.

NOTE !
The classification according to standard IEC/EN 60601-I - Type of protection against electric shock : Class I - Degree of protection against electric shock : Type B - Degree of protection against harmful ingress of water : IPX 0 - Methods of sterilization or disinfection : See Chapter 4.2.1 - Not suitable for use in the pressure of flammable anesthetic mixtures

4 **Check followings while the device is in operation.**

A) Whether the product and the patient are normal

B) Whether the products keep distances with one another

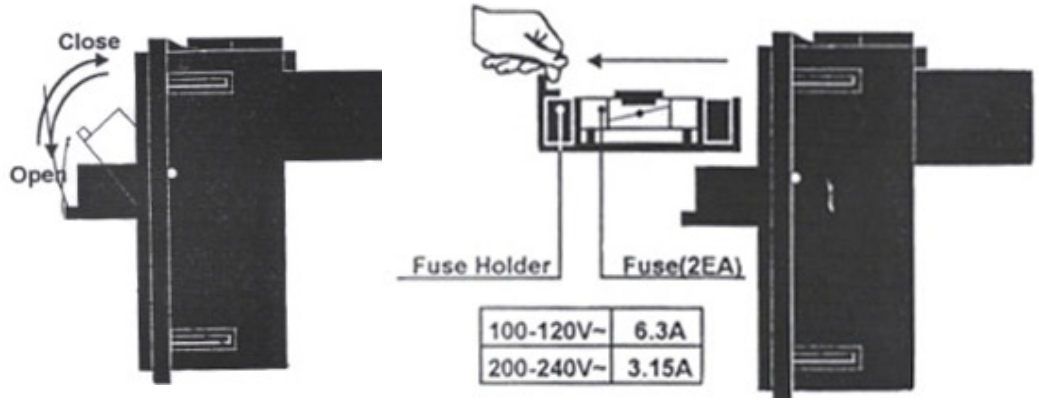
C) If you find any abnormality related to the product or patient, stop its operation and check if it can cause any danger to the patient.

D) EXA-3000 uses X-ray. If there are any other substances (socks or clothes) between diseased part and X-ray source or detector, the device cannot take accurate measurement. Accordingly, take measurement when there are no foreign substances on the diseased part.

E) If the fuses are gone, exchange the same type (250V T315AL). Otherwise a fire may occur or you may receive electric shock.

NOTE !

Fuse Replacement



1. Open the fuse drawer on the upper side of the appliance inlet, there will be the two small fuse holders.
2. Push the fuse holder toward the arrow direction, and Pull the fuse holder toward the upper side of the appliance inlet.
3. Remove the old fuse by pulling up
4. Install the new fuse by pushing to the fuse holder.
5. Insert the fuse holder to the appliance inlet. At this time, the arrow direction in the upper side of the fuse holder should be in accordance with that on the fuse draw.
6. Also, the same method is used to exchange the other fuse folder.
7. Close the fuse the drawer.

CAUTION !

For continuous protection against a risk of fire hazard, replace only with same type and same rating of fuse.

5 **Checking points after use of product**

A) Make sure to clean the product so that use Deactivate the product and turn the power off in order.

B) Do not pull the power cord forcibly.

C) Comply with followings to keep the product properly.

① Avoid places that can wet the product.

② Avoid places where air pressure, temperature and humidity drastically change and where there are direct ray of sun, dirt, salt and sulfur.

③ Do not lean, shake or rock the product.

D) Clean accessories after use.

E) Make sure to clean the product so that users can use it immediately

6 **If the product is out of order, do not try to repair it for yourself.**

7 **Do not modify use the product. If any modification is desired, ask OsteoSys or its authorized dealer for this service.**

8 **Check, maintenance and repair**

9 **Cautions in times of transportation of cart**

If you have to move the cart on incline floor, you should detach the product from the cart so that the product does not slip to the ground.

10 **Environmental protection**

If the products are at the end of their useful lives, do not dispose them at your option. Contact OsteoSys or its authorized dealer for this service.

11 **Others**

Read the user's instructions carefully and use the product properly.

Chapter 5. Specifications & Software Updates

5.1 Specifications

5.2 Software Updates

5.1 Specifications

***General**

Classification	Class Ⅰ, Type B Applied part

***Scanning Unit**

Dimensions	670 mm x 410 mm x 373 mm
Weight	27.45 KG
Input Voltage	AC 100V~240V, Free Voltage (Single Phase)
Frequency	50/60 Hz
Power	Max. 300W

***Precision**

In Vitro	± 1% CV
In Vivo	± 2% CV

***Accuracy**

**Imaging

Imaging Area	100 mm x 100 mm
Exposure Time Accuracy	1.5sec(High), 1.0sec(Low)
Angle of Reference Axis	5°
Focal Spot to Image Receptor Distance	308mm
Nominal Shortest Irradiation Time	1 sec
Minimum Quality Equivalent Filtration	2.5mm Al

**Environmental

Operating Temperature	18 ~ 27℃
Transport / Storage Temperature	-5 ~ 50℃
Operating Humidity	20 ~ 80% relative humidity
Transport / Storage Humidity	0 ~ 90% relative humidity, non-condensing
Atmosphere	700 ~ 1060 hPa
Shock	Not to exceed 2G in six millisecond
Dust, Fumes, Airborne debris	Install system in a clean, well-ventilated area. Excessive dust and other airborne debris contaminants can impair sensitive parts. We recommend instituting a "No Smoking" policy in system area

***X-ray Source**

**Tube Housing :

Manufacturer	OsteoSys Co., Ltd
Manufacturer Address	3F, 308 , Byuksan DigitalValley 3rd, 212-13, Guro-Dong, Guro-Gu, Seoul, Korea Tel : 82-2-2025-1650 Fax : 82-2-2025-2299
Model	HTB-032
Nominal Tube Voltage	80 kV(High), 55 kV(Low)
Nominal Tube Current	0.4 mA
Input Voltage	24V DC ~ 15V DC
Nominal Electric Power	50 W
Maximum Output Power	40 W
Filtration	○ Inherent Filter : 3.0 mm Al, ○ Added Filter - 80 kV : Filter Wheel ~ 0.8mm Brass (Zn 30% + Cu 70%) - 55 kV : 1.6mm Polycarbonate (X-ray window 2.5 mm Al)

Shutter	2 mm Pb
Loading Factors for Maximum Energy Input at Nominal kV	80 kV, 0.4 mA
Maximum Continuous Heat Dissipation	25 W
Maximum X-ray Tube Assembly Heat Content	183,000 J
Maximum Symmetrical Radiation Field	○ Distance : 180mm ○ Field size: 50mm x 50mm
Reference Axis	○ Angle : 5degree with respect to the image receptor ○ Location : from the focal spot to the center of the image receptor
Focal Spot to Image Receptor Distance	300 mm

**X-ray Tube :

Manufacturer	Superior X-ray
Manufacturer Address	1220 Claussen Drive Woodstock, IL 60098 * Tel : (815)338-4424 * Fax : (815)338-9452 * E-mail : info@superiorxraytube.com
Model	SXR-80-14-2P
Nominal Focal Spot Value	0.25 mm
Cathode	Tungsten Filament
Anode	14 Stationary, Tungsten Target
Max. Tube Voltage	80 kV
Max. Tube Current	15 mA
Nominal Anode Input Power	150 W
Inherent Filtration/Window Material	1.5 mm / Glass
Single Load Rating	80 kV, 10 mA
Series Load Rating	95 kV, 8.5 mA, 4 loading/sec

Chapter 6 . Product Warranty

● Scope and Period of Warranty

(1) HFS, Ltd. guarantees all new products against faults in materials or workmanship for a period of one year from date of shipment to purchaser. OsteoSys Co., Ltd. will, as sole and exclusive remedy, at no charge, replace any such defective unit returned to its service designated warranty period.

(2) This warranty applies only to failures from operating the product under conditions for which it was designed. Warranted product is to be used only for the intended and labeled indications presented in the literature accompanying the product.

(3) HFS, Ltd. will charge service fees in following cases.
- If the product is out of order after the warranty period expires.
- If the product is out of order due to natural disasters such as fire, flood, windstorm, hail, lightning and earthquake.
- If the product is out of order due to improper transportation after installation and careless use.
- If the product is out of order due to improper repair or renovation by someone other than service personnel of the company.

(5) Cosmetic defects or deterioration will not be refinished or replaced. The costs of replacement of fuses are not covered.

(6) HFS, Ltd. will not be responsible for any loss, damage, or injury resulting from delay in rendering service under this warranty.

(7) HFS, Ltd. will not be responsible to you for incidental or consequential damages of any kind arising from or connected with the use of its equipment.